CURRICULUM VITAE
Tara Lee Frenkl, MD, MPH

A dynamic and innovative senior pharmaceutical industry executive with extensive experience in strategic drug development across multiple therapeutic areas, including Oncology, Immunology, Urology, and Women's Health. A proven track record in leading clinical research, global drug development, and registration filing/approval processes for pharmaceuticals and devices. Possesses comprehensive expertise in managing complex projects, collaborating with industry and non-for-profit partners. Demonstrated leadership in fostering talent development, empowering her team, and enhancing organizational effectiveness. Built and led high- performance teams, fostering a culture of urgency, collaboration, innovation, and excellence. Exceptional communication, organizational, and presentation skills complemented by a diversified education in pharmacy, medicine and public health. Recognized for contributions to key initiatives and awarded for outstanding performance in pharmaceutical innovation and leadership.

Highlights

- Senior pharmaceutical industry leader with experience in clinical practice, clinical research, and global drug development. Able to design and execute clinical trials intended for global registration across multiple therapeutic areas.
- Pharmaceutical Industry Representative to FDA Oncology Drugs Advisory Committee (term 2024-2027).
- Breath of experience across portfolios in multiple modalities, mechanisms, and indications, principally in Oncology (monoclonal antibodies, small molecules, ADCs, radioligand therapy; inhibitors of PD-1, PARP, HER2, Necitin-4, BCMA, androgen receptor, + others) and Women's Health (drug-device combinations utilizing synthetic and naturally derived hormonal agents for contraception, fertility, dysmenorrhea, and post-partum hemorrhage, and NK-1 inhibitors and beta3 agonists for overactive bladder)
- Registration Filing /Approval Experience for drugs and devices including pembrolizumab for multiple lines of bladder cancer, darolutamide for prostate cancer, carbetocin for postpartum hemorrhage after vaginal delivery, and NuvaRing Applicator.
- Wide-ranging global labeling and regulatory experience including agency meetings, benefit risk assessment, risk management plans, safety label updates, variations, and device risk management activities.
- Extensive experience with collaboration for drug development including WHO, Janssen, Zai Lab, Merck-KGaA, SeaGen, Takeda, and iTEOs.
- Leading and founded the ACE Alliance with nonprofit organization, CEO Roundtable on Cancer and National Minority Quality Forum, to improve the health of those disproportionately affected by cancer through increasing access, choice, and education (ACE) to clinical trials.
- Proven leadership, communication, and management skills with passion for developing others.

EDUCATION:

Rutgers University College of Pharmacy New Brunswick, NJ	B.S., Pharmacy Salutatorian Class President 3 years Phi Lambda Sigma Phi Eta Sigma Rho Chi Society
Rutgers-Robert Wood Johnson Medical School	M.D. Alpha Omega Alpha
Rutgers University, School of Public Health	M.P.H.

CLINICAL AND RESEARCH TRAINING:

Duke Medical Center Durham, NC	Intern Dept. of Family Practice
Duke Clinical Research Institute Faculty head, Dr. Chris O'Connor Durham, NC	Research Coordinator Cardiology Trial
The Warren Alpert Medical School of Brown University Providence, RI	Resident Dept. of Surgery, Div. of Urology
The Cleveland Clinic Glickman Urologic and Kidney Institute Cleveland, OH	Fellow in Female Pelvic Medicine and Reconstructive Surgery

POSITIONS:

6/2024-present	Senior Vice President Head, Global Medical Strategy and Evidence Generation Bayer Pharmaceuticals International Assignment- Whippany, NJ and Basel, CH
1/2024-present	Pharmaceutical Industry Representative to US FDA Oncology Drugs Advisory Committee
4/2022-5/2024	Senior Vice President Head of Oncology Development Oncology Strategic Business Unit Bayer Pharmaceuticals International Assignment - Whippany, NJ and Basel, CH
2021-2022	Senior Vice President Head of Medicine Development Leaders, Oncology GlaxoSmithKline Collegeville, PA
2019-2021	Vice President Medicine Development Lead, Niraparib New Indications beyond Ovarian Cancer, Oncology GlaxoSmithKline Collegeville, PA
2016-2019	Executive Director, Oncology Product Development Team Lead, Pembrolizumab for Bladder Cancer Merck Research Labs, Merck & Co., Inc. Upper Gwynedd, PA
2014-2016	Executive Director, Endocrine and Women's Health Therapeutic Area Section Head of Women's Health Merck Research Labs, Merck & Co., Inc. Upper Gwynedd, PA
2010-2014	Senior Principal Scientist of Clinical Research Women's Health, 2013-14 Respiratory and Immunology, 2010-13 Merck Research Labs, Merck & Co., Inc. Upper Gwynedd, PA
2006-2010	Associate Director of Clinical Research Immunology, Analgesia, Anemia and Urology Merck Research Labs, Merck & Co., Inc. Upper Gwynedd, PA
2008-2022	Adjunct Clinical Staff Division of Urology Hospital of the University of Pennsylvania Philadelphia, PA
2005-2006	Assistant Professor, Division of Urology Director, Center for Female Pelvic Medicine and Reconstructive Surgery UMDNJ, Robert Wood Johnson Medical School New Brunswick, NJ

CURRENT LICENSURE & BOARD CERTIFICATICATION

Medical Licensure:	Pennsylvania
Certifications:	National Board of Medical Examiners American Board of Urology

LEADERSHIP DEVELOPMENT PROGRAMS

Nomination based participation in innovative leadership development programs created in partnership between employer and external education institutions.

CNEXT	C-suite Leadership Development	2023+
Harvard Business School	Merck Emerging Leader Program	2016
Harvard Business School	Merck Build the Best Teams and Talent	2016
Merck Learning and Dev	MRL Business Acumen Program	2016
Wharton School	Merck Executive Leadership Program	2015
Merck Women's Sponsorship Program	Sponsor- Peter Paris Stein	2015-6
Harvard Business Publishing	Leaders Connect	2013-4
Simmons School of Management	Merck Women's Leadership Program	2012
Rutgers University	Mini-MBA BioPharma Innovations Program	2011

DEVELOPMENT AND REGULATORY EXPERIENCE

- **Clinical Trial Design and Execution**

Associate to Senior Director of Clinical Research (2006-2014), Merck

1. A Phase 2b, Randomized, Double-blind, Placebo-controlled, Dose ranging study of Serlopitant in Patients with Overactive Bladder (MK-0594-003, 2006 -2007)
2. A Phase 1 Randomized, Placebo Controlled, Crossover Study to Evaluate the Effects of Tolterodine Tartrate on Urodynamic Parameters in Patients with Overactive Bladder (MK-0000-107, 2008-2009)
3. A Phase 3, Double-Blind, Placebo-Controlled, Multicenter Trial to Study the Efficacy and Tolerability of MK0663/Etoricoxib in the Treatment of Pain After Abdominal Hysterectomy (MK-0663-097, 2008-2010)
4. A Phase IIb Randomized, Placebo- and Active Comparator (Tolterodine)- Controlled, 2-Part Clinical Study of the Efficacy and Safety of MK- 4618 (vibegron) in Patients with Overactive Bladder (MK-4618-008a, 2011- 2012)

5. A 52-week Extension to: A Phase IIb Randomized, Placebo- and Active Comparator (Tolterodine)-Controlled, 2-Part Clinical Study of the Efficacy and Safety of MK-4618 (vibegron) in Patients with Overactive Bladder (MK-4618-008b, 2011-2013)
6. A Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled Study of the Effect of Golimumab Administered Subcutaneously in Subjects with Active Axial Spondyloarthritis (MK-8259-006-02, 2012-2014)

Section Head of Women's Health, Clinical Development (2014-2016), Merck

7. A Phase 2 Randomized, Placebo-controlled Clinical Trial to Evaluate the Effect of Contraceptive Vaginal Rings on Primary Dysmenorrhea (P08257/MK-8175A/MK-8342B-057, 2012-2017)
8. A Phase 3, Randomized Double Blind Study Efficacy and Safety of Etonogestrel + 17β-Estradiol Vaginal Ring (MK-8342B) in Women with Primary Dysmenorrhea (With Optional Extension) (MK-8342B-059, 2016- 2016)
9. A Phase 3, Randomized Double Blind Study of the Efficacy and Safety of Etonogestrel + 17β-Estradiol Vaginal Ring (MK-8342B) in the Treatment of Women with Primary Dysmenorrhea (MK-8342B-060, 2016-2016)
10. A Phase 3 Single Arm Trial of Efficacy and Safety of Etonogestrel + 17β- Estradiol Vaginal Ring in Women at Risk for Pregnancy (MK-8342B-061, 2015-2016)
11. A Phase 3, Randomized, Active-Comparator Controlled Clinical Trial to Study the Contraceptive Efficacy and Safety of the MK-8342B (Etonogestrel + 17β-Estradiol) Vaginal Ring and the Levonorgestrel-Ethinyl Estradiol (LNG-EE) 150/30 µg Combined Oral Contraceptive (COC) in Women at Risk for Pregnancy ((MK-8342B-062, 2015-2016)
12. A Multicenter, Open Label, Randomized, Two-period Crossover Study on the Insertion of MK-8342A (NuvaRing®) Placebo with and without the Use of NuvaRing Applicator in Healthy Female Subjects ((MK-8342A-063, 2014-2015)
13. A Phase 3, Randomized, Placebo-Controlled Study of Heat-Stable Carbetocin versus Oxytocin to Prevent Hemorrhage after Vaginal Birth (CHAMPION Study with World Health Organization, 2015-2018)

Product and Clinical Development Lead (Pembrolizumab, Bladder Cancer 2016-2019), Merck

14. A Phase 3 Study of Pembrolizumab (MK-3475) Versus Paclitaxel, Docetaxel, or Vinflunine for Participants with Advanced Urothelial Cancer (KEYNOTE-045, 2014-2017)
15. A Phase 2 Study of Pembrolizumab (MK-3475) in Participants with Advanced Urothelial Cancer (KEYNOTE-052, 2015-2019)
16. A Phase 2 Study of Pembrolizumab (MK-3475) and Pembrolizumab in Participants with High Risk Non-muscle Invasive Bladder Cancer (KEYNOTE-057) (2014-2019)
17. A Phase 3 Randomized, Double-Blind Trial Study of Pembrolizumab with or Without Platinum-based Combination Chemotherapy Versus Chemotherapy Alone in Urothelial Carcinoma (KEYNOTE-361, 2C016-2021)
18. A Phase 3 Randomized, Double-Blind Trial of Pembrolizumab (MK-3475) in Combination with Epacadostat (INCB024360) or Placebo in Participants with Cisplatin-ineligible

Urothelial Carcinoma (KEYNOTE-672/ECHO-307, 2017-2018)

19. A Phase 3 Randomized Double-Blind Trial Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Bacillus Calmette-Guerin (BCG) in High-Risk Non-Muscle Invasive Bladder Cancer (HR NMIBC) (KEYNOTE-676, 2018)
20. A Phase 3 Randomized, Double-Blind Perioperative Pembrolizumab (MK- 3475) Plus Cystectomy Plus Cystectomy Versus Cystectomy Alone in Participants Who Are Cisplatin-ineligible or Decline Cisplatin with Muscle- invasive Bladder Cancer (KEYNOTE-905, 2018)
21. A Phase 3 Randomized, Double-Blind Perioperative Pembrolizumab (MK- 3475) Plus Neoadjuvant Chemotherapy Versus Perioperative Placebo Plus Neoadjuvant Chemotherapy for Cisplatin-eligible Muscle-invasive Bladder Cancer (MIBC) (KEYNOTE-866, 2019)
22. A Phase 3 Randomized, Double-Blind Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Chemoradiotherapy (CRT) Versus CRT Alone in Muscle-invasive Bladder Cancer (MIBC) (KEYNOTE-992, 2020)

Product and Clinical Development Lead (Niraparib, 2019-2021), GSK

23. Efficacy and Safety Comparison of Niraparib to Placebo in Participants with Human Epidermal Growth Factor 2 Negative (HER2-) Breast Cancer Susceptibility Gene Mutation (BRCAmut) or Triple-Negative Breast Cancer (TNBC) With Molecular Disease (positive ctDNA) (ZEST, 2021)
24. A Phase III, Randomized, Placebo-controlled Study Comparing Niraparib Plus Pembrolizumab Versus Placebo Plus Pembrolizumab as Maintenance Therapy in Participants with Advanced/Metastatic Non-small Cell Lung Cancer (ZEAL- 1L, 2020)
25. A Phase 1, Multicenter, Open-label, Dose Escalation and Cohort Expansion Study of Niraparib and Dostarlimab in Pediatric Participants with Solid Tumors (SCOOP, 2020)

- **Registration Filing/Approval Experience (Select)**

1. Global Approval including US, EU, China, Japan, plus 70+ other countries (RTOR, Project Orbis): Darolutamide in combination with docetaxel for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC). (2022-2023, Head of Oncology Development, Bayer)
2. EU Renewal 2023-2024 for larotrectinib for treatment of adult and pediatric patients with solid tumors that display a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion (2023, Head of Oncology Development, Bayer)
3. US Approval: Pembrolizumab for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy. (2020, Clinical and Product Development Team Lead- completed submission package, Merck)
4. US Accelerated Approval: Pembrolizumab for the treatment of patients with locally advanced or mUC who were not eligible for cisplatin-containing chemotherapy as determined by an FDA-approved test, or in patients who were not eligible for any platinum-containing chemotherapy regardless of PD- L1 status 2017, revised based on new data in 2018 to patients whose tumors expressed PD-L1 (Combined Positive Score

[CPS] ≥10), (2017-2018, Clinical and Product Development Team Lead)

5. Global "conditional" and full approvals including EU, Canada, Australia and multiple other countries: Pembrolizumab for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin- containing chemotherapy and whose tumors express PD-L1 with a combined positive score (CPS) ≥10 (2017-2019, Clinical and Product Development Team Lead)
6. Global Approval including US, EU, Japan, Australia, and other countries: Keytruda as monotherapy is indicated for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum- containing chemotherapy (2017-2019, Clinical and Product Development Team Lead)
7. Swissmedic Approval: Heat-stable carbetocin for the prevention of post-partum hemorrhage – the first medicine approved under the Swissmedic and Marketing Authorization for Global Health Products (MAGHP) procedure which aims to build capacity and speed up access to essential medicines in low- and middle- income countries. (2019, Merck for Mothers Scientific Consultant)
8. US Approval: NuvaRing Applicator, 2016 (Clinical and Product Development Team Lead)
9. EU CE Mark: NuvaRing Applicator. 2016 (Clinical and Product Development Team Lead)

- **<u>Health Authority Consultations (Select)</u>**
  1. FDA EOP2/Pre-Phase 3 and EMA Scientific Advice Meetings
     - Regorafenib in combination with fluoropyrimidine, chemotherapy and nivolumab for maintenance treatment of HER2-metastatic gastric / GEJ adenocarcinoma
     - Niraparib plus Pembrolizumab as Maintenance Therapy in Advanced/ Metastatic Non-small Cell Lung Cancer
     - Niraparib for HER2 negative Breast Cancer BRCAmut or Triple-Negative Breast Cancer (TNBC) With Molecular Disease (positive ctDNA)
     - Pembrolizumab in Combination with Bacillus Calmette-Guerin (BCG) for High-Risk Non-Muscle Invasive Bladder Cancer (HR NMIBC)
     - Pembrolizumab for Muscle Invasive Bladder Cancer Studies
     - Etonogestrel + 17β-Estradiol Vaginal Ring (MK-8342B, Next GenerationVaginal Ring) for Indications of Contraception and Dysmenorrhea
     - MK-4618 (Vibegron) for Overactive Bladder
     - NuvaRing Applicator for vaginal ring insertion
  2. FDA End-of-Phase 1 Meeting
     - mHER2 EGFR inhibitor (BAY 2927088) for NSCLC
  3. FDA SEALD Meeting
     - Bladder Diary PRO as primary endpoint in overactive bladder studies
     - Novel Pain PRO as primary endpoint for dysmenorrhea studies for Next Generation Vaginal Ring
  4. FDA pre-sBLA meeting
     - Pembrolizumab in High Risk Non-muscle Invasive Bladder Cancer
  5. FDA Voluntary Withdrawal
     - ALIQOPA NDA Withdrawal and Opening of Expanded Access Program
  6. FDA Break Through Designation

- mHER2 EGFR inhibitor (BAY 2927088) for NSCLC
    - Initial Comprehensive Multidisciplinary Breakthrough Designation

7. Health Canada Consultations
    - MK-4618 (Vibegron) for overactive bladder
    - MK-8432-B (Next Generation Vaginal Ring) for indications of Contraception and Dysmenorrhea
    - Pembrolizumab in Combination with Bacillus Calmette-Guerin (BCG) in High-Risk Non-Muscle Invasive Bladder Cancer (HR NMIBC)
8. PMDA Consultations
    - Pembrolizumab for Locally Advanced or Metastatic Urothelial Carcinoma in Adults Who Have Received Prior Platinum-containing Chemotherapy
    - EOP2 for Vibegron for Overactive Bladder

- **Industry Representative to FDA Oncology Drugs Advisory Committee**

1. **14Mar2024 NDA #217779, Geron Co.;** Discussion of whether efficacy of imetelstat (RYTELO®), a first-in-class telomerase inhibitor, for the treatment of transfusion-dependent anemia in adult patients with low-to intermediate-1 risk myelodysplastic syndromes who have failed to respond, lost response, or are ineligible for erythropoiesis stimulating agents was demonstrated in Study 63935937MDS3001 and if the benefits outweigh the risks of treatment.
2. **15Mar2024 morning session, sBLA 125746.74, Janssen Biotech, Inc;** Discussion focused on the overall survival data in the Study MMY3002 (CARTITUDE-4) and the risk and benefit of ciltacabtagene autoleucel (cilta-cel), an autologous, anti-B-cell maturation antigen (BCMA), chimeric antigen receptor engineered T cell (CAR T) therapy, for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least one prior line of therapy, including a proteasome inhibitor, and an immunomodulatory agent, and are refractory to lenalidomide.
3. **15Mar2024 afternoon session, sBLA 125736.218, Celegene/BMS Bristol-Myers Squibb Co;** Discussion focused on the overall survival data in the Study MM-003 (KarMMa-3) and the risk and benefit of idecabtagene vicleucel (ABECMA (idecabtagene vicleucel, ide-cel), an autologous BCMA CAR-T therapy, for the treatment of adult patients with relapsed/refractory multiple myeloma who have received an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
4. **12Apr2024: Use of Minimal Residual Disease (MRD) as an Endpoint in Multiple Myeloma Clinical Trials;** Discussion focused on the use of minimal residual disease (MRD) as an endpoint in multiple myeloma clinical trials, including considerations regarding timing of assessment, patient populations, and trial design for future studies that intend to use MRD to support accelerated approval of a new product or a new indication.
5. **22May2024: Pediatric Oncology Subcommittee of the ODAC;** Discussion focused on amendments made by Section 504 of the 2017 FDA Reauthorization Act (FDARA) to section 505B of the Food, Drug, and Cosmetic Act required, for original applications submitted on or after August 18, 2020 for pediatric investigations of certain targeted cancer drugs with new active ingredients, based on molecular mechanism of action rather than clinical indication. The Subcommittee discussed the perspectives relating to implementation of this legislation and its impact on pediatric cancer drug development, role of nonclinical proof-of -concept studies, and role of pediatric clinical trial networks and international colloboration.
6. **25July2024: BLA# 761069/S43**, AstraZeneca; Discussion focused on whether additional trials should be conducted to clarify the contribution of treatment phase for the durvalumab perioperative regimen for te treatment of resectable NSCLC prior to approval. In addition, the committee discussed whether FDA should require new trial design proposals for perioperative regimens for resectable NSCLC including adequate within trial assessment of contribution of treatment phase.
7. **7Nov2024: DEN220077** General and Plastic Surgery Device Panel Meeting for Denovo submission for Ice Cure Medical for the ProSenseTM Cryoablation System for an indication for early breast cancer.

Executive Leadership Responsibilities (Select)

- **As Head of Global Medical Strategy and Evidence Generation at Bayer**
    - Led large scale organizational change, achieving a unified vision for medical affairs and integrated evidence generation with significant cost savings and improved efficiency using VACC leadership principles
    - Augmenting capabilities for the global medical affairs and evidence generation organization across all therapeutic areas to create strategies including launch planning, real-world generation, market access strategy, pipeline development, and business development evaluations.
    - Enhancing Data and Advanced Analytics capabilities both internally and through external partnerships to optimize evidence generation, drive innovation and improve decision-making,
    - Oversees the development and implementation for global medical affairs strategies by the product development teams across all therapeutic areas (Oncology, Cardiovascular and Renal, Cell and Gene Therapy, Immunology, and Women's Health).
    - Provide medical leadership in terms of governance, ethical conduct, and standards of medical practice and collaborates with the Chief Medical Office to ensure compliance with regulation while advocating for patient-centered care and maintenance of highest ethical standards.
    - Responsible for all activities related with Phase IV study programs (interventional, non-interventional), investigator-initiated research and trials, and expanded access programs, including compliant handling.
    - Enable the development and implementation of global publication plans and external engagement.
    - Oversee the development of real-world evidence plans to create innovative regulatory opportunities and drive cross development expertise on novel approaches for evidence generation leveraging advanced analytics and machine learning/AI.
    - Ensure excellence in Data Science, Research, Analytics, and Integrated Evidence Generation study operations.

- **As Head of Oncology Development at Bayer**

    - Responsible for directing Development activities for Bayer's Oncology portfolio and for key Development functions including Regulatory Affairs, Data Analytics and Statistical Sciences, Clinical Operations, and Project Management for all Oncology, and Clinical Development for late-stage Oncology
        - Bayer portfolio: NUBEQA® (darolutamide); XOFIFO® (Radium 223); VITRAKVI® (larotrectinib), STIVARGA® (regorafenib); ALIQOPA® (copanlisib). Early pipeline focused on targeted radiotherapy, immuno-oncology and precision medicine candidates.
    - Corporate Governance Responsibilities:
        - Member of Pharmaceutical Global Leadership Council
        - Co-Chair Oncology Sounding Board – technical and scientific review of medicine and clinical development plans
        - Voting member, One Oncology Committee- approval of clinical phase advancement of new candidates
        - Voting Member, Global Safety and Labeling Committee
        - Voting Member, Research Portfolio Review Committee

development, and Patent Reported Outcomes, Achieving Market Access Success for Oncology Combinations, and Bridging the Gap: From Statistical Method to Better Clinical Trials.

- Initiated (2023) and leading the **ACE Alliance** with the non-profit organization, CEO Roundtable on Cancer and National Minority Quality Forum via biopharma leadership which aims to create a more inclusive and equitable framework for conducting cancer research and to ensure the advances in treatment are accessible to all, particularly those who have historically been marginalized. Partners include other pharma, academics institution, SAS, National Minority Quality Forum, Brand Institute and other nonprofit organizations. On target to establish 4 new clinical trial sites in 2024 in underserved areas of Flint Michigan, Houston, Louisiana, and North Carolina.

- **As Head of Medicine Development Leaders, Oncology at GSK**

  - Member of GSK Development Review Committee (technical and scientific review of medicine and clinical development plans) and Portfolio Investment Board

  - Accountable for Oncology portfolio prioritization which included NY-ESO and NextGen Cell and Gene Therapy assets, ZEJULA®, JEMPERLI®, BLENREP®, cobolimab (anti-TIM-3), anti-TIGIT, and anti-CD96

  - Joint Steering Committee and Co-Chair Roles across GSK partnerships including Takeda, Zai Lab, Janssen, iTeos and Merck Serono

  - Member of multiple internal Steering Committees for improvement initiatives across GSK Global Development
    - Digital Data and Technology Acceleration
    - Accelerating Submissions
    - Oncology People and Culture Pillar (Chair)
    - Simplification
    - Development Quality Council

- **As Vice President, Medicines Development Lead- ZEJULA (niraparib) New Indications Beyond Ovarian Cancer**

  - Strategically led the global development of niraparib and novel combinations from FIH to approval for indications beyond ovarian cancer. Development programs initiated include 1L NSCLC maintenance lung cancer, Phase 2/3 breast cancer using ctDNA to identify patients, pediatric program evaluating niraparib+ dostarlimab in osteosarcoma and neuroblastoma, and Phase 1 dose escalations with novel combinations.

  - Led the Medicine Development Team, integrating all R&D and commercial disciplines to develop and execute a clinical development plan that would lead to global registration (including clinical development, medical affairs, safety, regulatory, commercial, CMC, and regulatory amongst others).

  - Asset single point of accountability and spokesperson to senior management (e.g., Head of Development, CMO, President of Pharma, Development Review Board and Portfolio Investment Board), governance boards and external advisory committees.

  - Member of Joint Development Teams and Joint Steering Committee for partnerships

with Zai Lab (China), Takeda (Japan), and Janssen (global for the development of prostate cancer).

- Partnered with Business Development and Translational Medicine to evaluate licensing and acquisition opportunities to build and execute strategy for the Synthetic Lethality Research Unit.

- **<u>As Executive Director /Director of Clinical Research at Merck</u>**

  - **Vice-chair of the Product Development Team (PDT) Leader Effectiveness Team (2018-2019)** which led the continuous education of all PDT leaders across Merck Research Labs to align process, build leadership, and teach an onboarding course for new PDT leaders.
  - **Product Development Team Leader for KEYTRUDA® (pembrolizumab) for Bladder Cancer**
    - Led a high-performance development team consisting of commercial, regulatory, safety, outcomes research, and project management representatives to create and execute on an end-to-end development strategy that would ensure regulatory and commercial success for KEYTRUDA® in all stages of bladder cancer
    - Novel indications achieved in 1L and 2LmUC, and non-muscle invasive blader cancer
  - **Expert Clinical Consultant for Merck for Mothers** (2013-2019) where I provided clinical and regulatory expertise for CHAMPION which was an unprecedented collaboration of Merck for Mothers with the **World Health Organization** and Ferring Pharmaceuticals to conduct a 30,000-woman global study conducted in developing countries as the basis for heat-stable carbetocin (a uterotonic) to prevent post-partum hemorrhage, and subsequently make it accessible to developing countries to reduce maternal mortality worldwide.
    - Results of the study were published in NEJM and were the basis for the inclusion of carbetocin in the WHO guidelines, and filing (sNDA) submitted to Swiss Medic in April 2019 with approval May 2020.
  - **Clinical Development Head of Women's Health**
    - Set the strategy and product development team deliverables for the contraception and fertility portfolio, including drug-device combinations, including Next Generation (vaginal) Ring, NEXPLANON® (progestin implant), ZOELY® (oral contraceptive), NuvaRing® (contraceptive vaginal ring) and NuvaRing applicator, and ELONVA® + legacy portfolio including IUDs
    - Product Development Team Leader of 5 teams in the Women's Health Franchise
    - Authored registration study and supported the filing of the NuvaRing applicator in the US and CE mark in EU
    - Merck-TEVA Development Committee and Steering Committee member
    - Obtained extensive labeling and regulatory experience including EOP2 meetings, safety label updates, EU Type 2 variations, and device risk management activities.
  - **Product Development Team Leader for Vibegron (GEMTESA®, Beta-3 agonist) for Overactive Bladder**
    - Delivered an integrated global program strategy (Phase I – III) including clinical studies to achieve registration including a global pediatric plan,

reimbursement, differentiation, life cycle management, and manufacturing/supply plan.

- Designed 4 Phase III protocols- product was then out-licensed to Kyorin and Urovant with subsequent successful registrations in Japan and the US respectfully.

- **Clinical Development Lead for Simponi® (golimumab) for rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis**
  - Worked collaboratively with marketing partner (Janssen Pharmaceuticals, Inc) to support clinical strategy and regulatory requests.
  - Provided medical leadership and collaboration with cross functional team, developed and monitored a Phase IIIB study for line extension for ankylosing spondylitis.

- **As Adjunct Clinical Staff, Div of Urology Hospital of the University of Pennsylvania**
  - Maintained a clinical practice ~ 2 days/month (no personal payment received) from 2008-2022

ACADEMIC AND PROFESSIONAL HONORS:

Bayer Top Performance Award Instilling Rigor and Discipline

Bayer Top Performance Award for Raising the bar - Development Forum

GSK Transformational Medicine Award – Niraparib NSCLC Study

Merck INSIPRE Awards for Foster Collaboration, Rapid Disciplined Decision Making

Merck PDT Leaders Award for Build the Best Teams

Merck INSPIRE Awards for Heroics during Cyberattack, and MRL Divisional Pipeline

Merck Rahway Team Award for Collaboration

Merck First in Man for Novel Compound

Merck Leadership in Clinical Development & Execution, Vibegron out-licensing

Merck and Co, Inc – 3 Performance based Awards of Excellence

Early Career Women Faculty Professional Development Seminar, Competitive entry seminar, co-sponsored by the American Academy of Medical Colleges and Harvard Medical School, July 8-11, 2006

Pfizer Scholars in Urology Award for Leadership, Innovation, and Outstanding Achievement in Urologic Science during Residency.

Janet M. Glasgow Memorial Achievement Citation, Recognition by the American Medical Women's Assoc of women who make the top 10% and are honor graduates

Alpha Omega Alpha, National Medical Honor Society

Geriatric Summer Fellowship, New Brunswick, New Jersey

Phi Lambda Sigma, National Pharmacy Leadership Society

Phi Eta Sigma, National Collegiate Honor Society

Herbert-Remmner Award, given by Pharmacology/Toxicology Department for academic excellence and leadership

Graduation Speaker, Pharmacy Class of 1992, Elected by faculty and peers

Merck- AFPE Gateway Scholar, Grant awarded to 4 undergraduate students in the US per year to support a promising research proposal in the pharma sciences

Rho Chi Society, National Colleges of Pharmacy Honor Society

Rutgers College of Pharmacy Research Honors Program

New Jersey Distinguished Scholar, Annual academic scholarship
Montclair Women's League College Scholarship, Academic scholarship

MEMBERSHIPS

CNEXT
American Society of Clinical Oncology
European Society of Clinical Oncology
American Urology Association

MANUSCRIPTS

1. *KEYNOTE-057: open-label, multicentre, phase 2 study of pembrolizumab monotherapy for the treatment of high-risk non–muscle invasive bladder cancer unresponsive to bacillus Calmette-Guérin*. Balar A, Kamat A, Kulkarni GS, Uchio EM, Boormans JL, Roumiguié M, Krieger L, Singer EA, Bajorin BF, Grivas P, Seo KY, Nishiyama H, Konety BR, Li H, Nam K, Kapadia E, **Frenkl T**, de Wit R. Lancet Oncology 021; 22: 919-30.

2. *Long-Term Outcomes in KEYNOTE-052: Phase 2 Study Investigating First-Line Pembrolizumab in Cisplatin- Ineligible Patients With Locally Advanced or Metastatic Urothelial Cancer*. Vuky, J, Balar A, Castellano D, O'Donnell PH, Grivas, P, Bellmunt J, Powles, T, Bajorin D, Hahn N, Savage M, Fang X, Godwin, JL, **Frenkl, T**, Moreno BH, de Wit, R, Plimack E. Journal of Clinical Oncology; 38(23) 2020.

3. *The Cost Effectiveness of Pembrolizumab versus Chemotherapy or Atezolizumab as Second-Line Therapy for Advanced Urothelial Carcinoma in the United States*. Slater RL, Lai Y, Zhong Y, Li H, Meng Y, Moreno BH, Godwin JL, **Frenkl TL**, Sonpavde, GP, Mamtani R. J Med Econ. 2020; 23(9): 967-77.

4. *Pembrolizumab as First-Line Therapy in Cisplatin-Ineligible Advanced Urothelial Cancer(KEYNOTE-052): Outcomes in Older Patients by Age and Performance Status*. Grivas, Plimack E, Balar A, Castellano D, O'Donnell PH, Bellmunt J, Powles, T, Hahn N, de Wit, R, Bajorin D, Ellison MC, **Frenkl TL**, Godwin, JL, Vuky J. European Urology Oncology 2020. 3: 351-7.

5. *KEYNOTE-676: Phase III study of BCG and pembrolizumab for persistent/recurrent high-risk NMIBC.* Kamat A, Shore N, Hahn N, Alanee S, Nishiyama H, Shariat S, Nam K, Kapadia E, **Frenkl T,** Steinberg G. Future Oncology 2020. 16 (10): 507–16.

6. *Pembrolizumab versus chemotherapy in recurrent, advanced urothelial cancer in Japanese patients: a subgroup analysis of the phase 3 KEYNOTE-045 trial.* Nishiyama H, Yamamoto Y, Sassa N, Nishimura K, Fujimoto K, Fukasawa S, Yokoyama M, Enokida H, Takahashi K, Tanaka Y, Imai K, Shimamoto T, Perini R, **Frenkl T**, Bajorin D, Bellmunt J. Int J Clin Oncol 2020 25(1):165-74.

7. *Systematic Literature Review and Meta-Analysis of Response to First-Line Therapies for Advanced/Metastatic Urothelial Cancer Patients Who Are Cisplatin Ineligible*. Freshwater T, Li,

Valiathan C, Li M, Perini R, Bracco OL, **Frenkl T,** Keefe S. American Journal of Clinical Oncology: Cancer Clinical Trials 2019 42(10): 802-9.

8. *Randomized phase III KEYNOTE-045 trial of pembrolizumab versus paclitaxel, docetaxel, or vinflunine in recurrent advanced urothelial cancer: Results of >2 years of follow-up.* Fradet Y, Bellmunt J., Vaughn DJ, Lee JL, Fong L, Vogelzang NJ, Climent MA, Petrylak DP, Choueiri TK, Necchi A, Gerritsen W, Gurney H, Quinn DI, Culine S, Sternberg CN, Nam K, **Frenkl TL**, Perini RF, De Wit R, Bajorin DF. Annals of Oncology 2019 30 (6): 970-6.

9. *Vibegron (RVT-901/MK-4618/KRP-114V) Administered Once-Daily as Monotherapy or Concomitantly With Tolterodine in Patients with an Overactive Bladder: A Multicenter, Phase IIb, Randomized, Double-blind, Controlled Trial Efficacy and Safety of Vibegron in Patients With Overactive Bladder.* Mitcheson D, Samanta S, Muldowney K, Pinto CA, Rocha B, Green S, **Frenkl TL**. European Urology 2019 75(2): 274-82.

10. *A phase 2b multicenter, randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of vaginal rings containing nomegestrol acetate or etonogestrel and 17β-estradiol in the treatment of women with primary dysmenorrhea*. Fox M.C., Klipping C., Nguyen A.M., **Frenkl TL,** Cruz S.M., Wang Y., Korver T. Contraception 2019 99 (2): 125-130.

11. *Phase II dose-finding study on ovulation inhibition and cycle control associated with the use of contraceptive vaginal rings containing 17β-estradiol and the progestagens etonogestrel or nomegestrol acetate compared to NuvaRing*. Duijkers I, Klipping C, Heger-Mahn D, Fayad GN, **Frenkl TL**, Cruz SM, Korver T. European Journal of Contraception and Reproductive Health Care 2018 23(4): 245-54.

12. *Pharmacological Characterization of a Novel Beta3 Adrenergic Agonist, Vibegron: Evaluation of Anti- Muscarinic Receptor Selectivity for Optimal Combination Therapy for Overactive Bladder.* Di Salvo J, Nagabukuro H, Wickham A, Stickins D, Abbadie C, DeMartino JA, Fitzmaurice A, Gichuru L, Kulick A, Donnelly ML, Jochnowitz N, Pereira A, Sanfiz A, Veronin G, Villa K, Woods J, Zamlynny B, **Frenkl TL**, Zycband e, Edmondson S, and Struthers M. Journal of Pharmacology and Experimental Therapeutics 2017. 360(2):346- 55.

13. *Safety and efficacy of the NuvaRing® Applicator in healthy females: A multicenter, open-label, randomized, 2- period crossover study.* Feldman R, **Frenkl TL**, Yacik C, Wang Y, Fox MC. Contraception 2016; 94: 362-5.

14. *Discovery of Vibegron: A Potent and Selective β3 Adrenergic Receptor Agonist for the Treatment of Overactive Bladder*. Edmondson SD, Zhu C, Kar NF, Di Salvo J, Nagabukuro H, Sacre-Salem B, Dingley K, Berger R, Goble SD, Morriello G, Harper B, Moyes CR, Shen DM, Wang L, Ball R, Fitzmaurice A, **Frenkl T**, Gichuru LN, Ha S, Hurley AL, Jochnowitz N, Levorse D, Mistry S, Miller RR, Ormes J, Salituro GM, Sanfiz A, Stevenson AS, Villa K, Zamlynny B, Green S, Struthers M, Weber AE. J Med Chem 2016 Jan 28;59(2):609-23.

15. *Perioperative use of etoricoxib reduces pain and opioid side-effects after total abdominal hysterectomy: a double-blind, randomized, placebo-controlled phase III study.* Viscusi ER, **Frenkl T,** Hartrick CT, Rawal N, Kehlet H, Papanicolaou D, Gammaitoni A, Ko AT, Morgan LM, Mehta A, Curtis SP, Peloso PM. Curr Med Res Opin 2012. 28(8): 1323-35.

16. *Evaluation of an experimental urodynamic platform to identify treatment effects: A randomized placebo- controlled crossover study in patients with overactive bladder.* **Frenkl T**, Railkar R, Shore N, Bailen J, Sutherland S, Burke J, Ruddy M, Beals C. Neurourology and Urodynamics 2012. 31(1):69-74.

17. *Variability of Urodynamic Parameters in Patients with Overactive Bladder.* **Frenkl T,** Railkar R, Palcza J, Scott B, Alon A, Green S, Schaefer W. Neurourology and Urodynamics 2011. 30:1565–9.

18. *A multicenter, double-blind, randomized, placebo-controlled trial of a neurokinin-1 receptor antagonist for overactive bladder.* **Frenkl T**, Zhu H, Reiss T, Seltzer O, Green S. Journal of Urology 2010. 184(2):616-22.

19. *Bladder Dysfunction in Mice with Experimental Autoimmune Encephalomyelitis.* Cengiz Z, Altuntas L, Daneshgari F, Guiming L, Adebola F, Kavran M, Johnson J, Gulen M, Jaini R, Li X, **Frenkl T**, Tuohy V. Neuroimmunol 2008.15;203(1):58-63.

20. *Management of iatrogenic foreign bodies of the bladder and urethra following female pelvic floor surgery.***Frenkl T**, Vasavada S, Rackley R, Goldman H. Neurourology and Urodynamics 2008. 27(6):491-495.

21. *Sexually Transmitted Infections.* **Frenkl T**, Potts J. Urologic Clinics of North America 2008. 35: 33-46.

22. *Tension Free Midurethral Slings.* Daneshgari, F, **Frenkl T**, AUA Update Series 2006. Vol 26; Lsn 3 American Urologic Association, Inc. Houston, Texas 2007.

23. *Office Based Transurethral Needle Ablation of the Prostate With Analgesia and Local Anesthesia.* Leocádio DE, **Frenkl T,** Stein, BS. Journal of Urology 2007. 178(5):2052-54.

24. *Results of Cystocele Repair: A Comparison of Traditional Anterior Colporrhaphy, Polypropylene Mesh and Porcine Dermis.* Handel LN, **Frenkl T**, Kim YH. Journal of Urology 2007. 178(1): 153-156.

25. *Sexually Transmitted Diseases. Part 1.* **Frenkl T**, Potts J. AUA Update Series 2006. Vol 25; Lsn 2. American Urologic Association, Inc. Houston, Texas 2006.

26. *Sexually Transmitted Diseases. Part 2.* Frenkl T, Potts J. AUA Update Series 2006. Vol 25; Lsn 3. American Urologic Association, Inc. Houston, Texas 2006.

27. *Injectable neuromodulatory agents: botulinum toxin therapy.* **Frenkl TL**, Rackley RR. Urol Clin North Am. 2005 Feb;32(1):89-99.

28. *The promise of therapy for complex voiding dysfunctions.* Rackley R, **Frenkl T**, Abdelmalak J. Botulinum Toxin: Contemporary Urology 2005:39-52.

29. *Pelvic hematoma as a cause of bladder perforation and gross hematuria*. Lane BR, Moy ML, **Frenkl T**, Hijaz A, Daneshgari F. Urology. 2004 Nov;64(5):1030.

30. *Results of a simplified technique for buried penis repair.* **Frenkl T**, Agarwal S, Caldamone

AA. Journal of Urology 2004. 171(2 Pt 1):826-8.

31. *Male Urinary Incontinence.* Kim Y, **Frenkl T**. Medicine and Health Rhode Island 2002. 85(5): 156-9.

32. *Transmucosal delivery of enkephalins: comparison of enhancing effects of dihydrofusidates and bile salts.* Sayani, A, Kim D, **Frenkl T**, Chun I, Chien Y. STP-Pharma Sciences 1994. 4(6):470-6.

BOOK CHAPTERS

1. Sexually Transmitted Diseases (Chapter 13) **Frenkl T**, Potts J. Campbell-Walsh Urology, 10th Edition. Ed: Wein A. Kavoussi L, Novick A, Partin A, and Peters C. Saunders, Philadelphia 2011.
2. Sexually Transmitted Infections (Chapter 25) **Frenkl T**, Potts J. Practical Urology: Essential Principles and Practice: Ed: Chapple CR and Steers WD, Springer 2011.
3. Sexually Transmitted Infections (Chapter 5). **Frenkl T**, Potts J. Genitourinary Pain and Inflammation. Ed: Potts J. Humana Press 2008.
4. Sexually Transmitted Diseases (Chapter 11). **Frenkl T**, Potts J Campbell's Urology, 9th Edition. Ed: Walsh P, Retik A, Vaughan ED, Wein A. Saunders, Philadelphia 2007.
5. Neuromodulation. Rackley R, **Frenkl T**. Urogynecology and Reconstructive Pelvic Surgery, 3rd Edition. Ed:Walters M, Karram M. Mosby, St. Louis 2006.
6. Conservative Management of Urinary Retention (Chapter 10) **Frenkl T**, Daneshgari F. Pelvic Floor Dysfunction: A Multidisciplinary Approach. Ed: Davila GW, Ghoniem GM, Wexner SD. Spring-Verlag 2006.
7. Other Therapies for Stress Urinary Incontinence (Chapter 6) **Frenkl T**, Vasavada S. Pelvic Floor Dysfunction: A Multidisciplinary Approach. Ed: Davila GW, Ghoniem GM, Wexner SD. Spring-Verlag 2006.
8. Surgical Management of Urinary Retention (Chapter 10) Rackley, R, **Frenkl T**. Pelvic Floor Dysfunction: A Multidisciplinary Approach. Ed: Davila GW, Ghoniem GM, Wexner SD. Spring-Verlag 2006.