

Vanessa N. Elharrar MD, MPH

Summary of Experience:

- Physician Executive with over 18 years of experience leading safety oversight and clinical development (Phase I-IV) for multiple domestic and international vaccine and HIV treatment and prevention clinical trial programs. Experience in the CRO, government (NIH/NIAID/ DAIDS), normative body (PAHO EPI) and non-profit settings. Currently Global Medical Officer, Vaccines and Government at PPD leading alliance management with Vaccine and Government sponsors. Board certified in Preventive Medicine. Experience leading teams in a matrixed and direct report structure.

Work History:

Pharmaceutical Product Development (PPD)

SEPTEMBER 2016- PRESENT

GLOBAL MEDICAL OFFICER, VICE PRESIDENT, VACCINES AND GOVERNMENT (OCTOBER 2020- present)

- Lead PPD strategy development to achieve business goals in the Vaccines TA in coordination with Commercial colleagues while developing existing and new accounts and assuring client needs are met.
- Engage with and support Biotech CEOs, CMOs and CSOs with outsourcing, clinical development and regulatory strategy.
- Global Product Development Vaccines Clinical Development Lead from February- May 2020 covering vaccines
- Organize and moderate Advisory Boards, KOL education and networking events (breakout sessions, roundtables, breakfasts etc.) and support PPD marketing activities.

EXECUTIVE DIRECTOR, REGIONAL MEDICAL OFFICER EUROPE/CENTRAL US

JANUARY 2019- SEPTEMBER 2020 (full time as of July 1, 2019)

VACCINES LEAD- CORONAVIRUS CLINICAL DEVELOPMENT

- Lead Coronavirus vaccine protocol development for the Moderna vaccine candidate and proposal development for other Coronavirus vaccine candidates
- Lead PPD strategy development to achieve business goals in Europe and Israel in coordination with Commercial colleagues while developing existing and new accounts and assuring client needs are met.
- Engage with and support Biotech CMOs and CSOs with clinical development and regulatory strategy.
- Organize and moderate Advisory Boards, KOL education and networking events (breakout sessions, roundtables, breakfasts etc.) and support PPD marketing activities.

MEDICAL DIRECTOR, APRIL 2018- JULY 1, 2019

ASSOCIATE MEDICAL DIRECTOR, SEPTEMBER 2016- APRIL 2018

Current as of June, 2024

- Protocol development for Vaccines, Infectious disease, CV, Ophtho and Oncology I- IV studies
- Perform medical review of Serious Adverse Events (AEs) to identify appropriate follow-up requests and to assess expectedness, seriousness and causality. Ensure appropriate content of safety narratives.
- Draft the DSUR and contribute to other regulatory submissions as well as the end of study report
- Medically monitor Vaccine and Phase I Oncology, Cardiovascular and Ophthalmology studies
- Handle subject inclusion/exclusion queries and subject management issues requiring medical judgment.
- Conduct aggregate review of safety and clinical trial data to ensure consistent reporting, medical logic, and appropriate coding.
- Provide therapeutic, protocol, and safety reporting training to internal teams at start-up and to sites at investigator meetings.
- Conduct medical review of clinical study reports and safety updates.
- Business Development activities to Network with new and existing clients.

NIH Office of the Director, Office of AIDS Research (OAR)

DIRECTOR, HIV THERAPEUTICS RESEARCH

FEBRUARY 2016- SEPTEMBER 2016

- Directly supervise staff
- Chair the Therapeutics Coordinating Committee in development of the Trans-NIH Plan for HIV-Related Research <http://www.oar.nih.gov/strategicplan/fy2016/pdf/FY-2016-Trans-NIH-Plan-for-HIV-Related-Research.pdf>
- Engage KOLs for input on the NIH HIV Therapeutics research portfolio and funding strategy
- Guide NIH funding policy for HIV/AIDS research grants and contracts
- Review and prioritize scientific applications for supplemental funding from OAR
- Prioritize key research in HIV Pre-Exposure Prophylaxis, Therapeutics and Prevention of Mother to Child Transmission for funding with AIDS dollars
- Directly supervise staff in support of these activities

NIH/National Institute of Allergy and Infectious Disease/Division of AIDS - Prevention Science Program/ Clinical Prevention Research Branch

DEPUTY BRANCH CHIEF (2011-2016), MEDICAL OFFICER and PROGRAM OFFICER

JULY 2007 – FEBRUARY 2016

Promoted to Deputy Branch Chief, Clinical Prevention Research Branch in the Prevention Sciences Program at the Division of AIDS/ NIAID/NIH (DAIDS) in 2011

- Lead clinical development for biomedical prevention products (injectable PrEP agents, Truvada, ART as Prevention) through clinical testing (Pre-Phase I and Phase I-III) with multidisciplinary teams of industry and academic KOLs in the HIV Prevention Trials Network (HPTN) and in non-Network studies.
 - Protocol development and review
 - Safety oversight during study conduct.
 - Serious adverse event review and reporting
 - Annual IND report development

Current as of June, 2024

- Contribute to analysis, interpretation, publication and presentation of findings at major meetings
- Successfully developed and launched Branch Initiatives and Funding Announcements (RFAs, PAs)
 - Methods for Prevention Packages Program (R01) RFA, now a PA
 - Innovative Measures of Oral Medication Adherence for HIV Treatment and Prevention (R01)
 - Serve at DAIDS representative to the HPTN Ethics Working Group
 - Serve as Program Officer for grants as assigned
- Organize scientific meetings and workshops to engage and elicit KOL input
 - Technical Convening on Clinical Trial Design Issues for Multipurpose Prevention Technologies (MPTs) (2016)
 - Planning committee, agenda development and speaker selection
 - Workshop on Quantitative Methods to Advance Combination Biomedical HIV Prevention Research (2011)
 - Meeting co-chair, moderator, agenda development, speaker selection
 - International Conference on HIV Treatment and Prevention Adherence (2011-2013)
 - Meeting faculty, abstract review, agenda development, panel moderator
 - Methods for Prevention Packages (MP3) Principal Investigators meeting (2011 and 2013)
 - Chief Organizer, moderator, agenda development
- Mentor staff and build capacity within the Branch

Henry M. Jackson Foundation

MEDICAL OFFICER

SEPTEMBER 2005 - JULY 2007

- Served as a Division of AIDS/NIAID contract Medical Officer for clinical trial protocols within the HPTN as well as non-Network R01 studies.
- Performed a Division of AIDS-wide qualitative evaluation of the Comprehensive International Program for Research on AIDS (CIPRA) grant mechanism.
 - Developed and validated interview questionnaires
 - Administered and coded over 100 qualitative interviews
 - Prepared a final written report detailing the findings
 - NIH Superior Performance Award received for the successful completion of this evaluation

Pan American Health Organization, Guatemala

SHORT TERM CONSULTANT

JULY 2004 - DECEMBER 2004

- Collaborated with a multidisciplinary team of KOLs, clinicians, epidemiologists, statisticians and public health staff from the Guatemalan Ministry of Health and the Pan American Health Organization to establish a hospital-based surveillance system for Rotaviral illness in three Guatemala City hospitals.
- Developed the surveillance protocol, manual of operations, case report forms, staff training

Current as of June, 2024

workshops, and budgets for this project along with Guatemalan colleagues.

Therapeutic Development Experience (highlights, full list available upon request):

Vaccine Development (PPD)

- clinical development lead for multiple COVID Vaccine programs. Protocol development, safety oversight and trend analysis and strict pause rule monitoring for Phase I-II Zika, Flu, Chikungunya, hMPV, PIV and Pertussis vaccines. SMC slide development and presentation, CSR development and IB review.

HIV Therapeutics and Prevention (NIH)

HPTN 052: HIV treatment strategy trial

- Large Phase III efficacy trial (N=1763 serodiscordant couples at 13 sites in 9 countries) of immediate vs delayed ART treatment effect on HIV transmission to seronegative partner and clinical course of the HIV-positive subject.
- This pivotal HIV treatment as prevention study shifted WHO and CDC guidelines to recommend that all HIV positive persons be treated immediately with ART, irrespective of CD4 count.
<https://www.nejm.org/doi/full/10.1056/NEJMoa1600693>
- HPTN 077, 078 and 083: Phase II and III studies testing the safety and efficacy of long-acting injectable antiretrovirals for the prevention of HIV (Cabotegravir, TMC 278LA, and GSK1265744 integrase inhibitor)
- For all HPTN studies, I was responsible for:
 - Safety oversight of the study
 - Oral presentation to FDA on study conduct and safety updates
 - KOL consultation to inform multiple protocol amendments due to shifting HIV treatment and prevention guidelines throughout the course of the study
 - Safety presentations to the DSMB
 - Publication development

HPTN 066, 067, 063, 075 and multiple R01 and U01 studies focusing on HIV prevention: Please see HPTN website: <https://www.hptn.org/research/studies>

Ophthalmology Therapeutics Development (PPD)

- Protocol development for Phase 1A and 1B and Phase II studying an intraocular injectable drug for AMD in the AMD patient population.
- Medical monitor for the Phase 1A and 1B studies, including targeted eligibility review, safety listing review, SAE review, site training, interaction with site PIs and reading center to answer protocol questions etc.

Cardiovascular Therapeutics Development (PPD)

- Protocol development for multiple Phase I studies of an investigational anticoagulant (antiplatelet agent) in both healthy volunteers and ESRD patients undergoing dialysis.
- Studies include SAD/MAD, food effect and drug-drug interaction when given with aspirin and/or Plavix.
- Responsible for safety oversight, development and presentation of Topline safety slides, CSR development and IB update based on study results.

Oncology Therapeutics Development (PPD)

Current as of June, 2024

- Protocol development for multiple Phase I studies of a small molecule inhibitor of the IDO1 enzyme. High IDO1 expression in cancers is correlated with more aggressive tumor progression and shorter patient survival time in most cancer types.
- Studies include SAD/MAD and drug-drug interaction when given with aspirin and/or Plavix.
- Responsible for safety oversight, development and presentation of Topline safety slides, CSR development and IB update based on study results.

Education:

Johns Hopkins Bloomberg School of Public Health

Preventive Medicine Residency

Masters in Public Health (MPH), *International Health*

Indiana University School of Medicine

Doctor of Medicine (MD)

McGill University Montreal, Canada

Bachelor of Science (BS), *physiology*

Training, Licenses and Certifications:

2003-2005 Public Health and Preventive Medicine Residency- Johns Hopkins School of Public Health

2002-2003 Internship- St. Vincent Hospital Indianapolis, IN

2003- present Physician License- Indiana- 01060513A

2006- present Board Certified in Public Health and Preventive Medicine

Skills:

Languages: French (Fluent/Native), Spanish (Fluent), English (Fluent/Native), Hebrew (Proficient)

Technical: STATA (Proficient), Microsoft Suite (Proficient)

Notable Distinctions:

PPD Vaccines received the ViE Award for Best CRO” in 2021 and 2022

PPD CEO Performance Excellence Award, 2017

Science Magazine Breakthrough of the Year, 2011. HIV Treatment as Prevention (HPTN 052). Science 23 December 2011: Vol. 334 no. 6063 p. 1628. I was the Medical Officer for this seminal study.

NIH Director's Award in recognition of outstanding leadership and management in the development of the site infrastructure, protocols, and implementation of HPTN 052/ACTG 5175 companion trials, 2012

NIAID Merit Award in recognition of significant contributions and exceptional teamwork by a trans-

Current as of June, 2024

NIAID team in the re-competition on the Leadership Groups for Clinical Research Networks, 2013-2014

NIAID Merit Award in recognition of participation in the development of the DAIDS Critical Events Identification Policies, 2011

NIH Superior Performance Award for conducting an evaluation of a grant mechanism, 2006

Publications:C

[American-Pharmaceutical-Review-2022-02-mRNA.pdf \(ppd.com\)](#)

Science Magazine Breakthrough of the Year, 2011. HIV Treatment as Prevention. Science 23 December 2011: Vol. 334 no. 6063 p. 1628.

Prevention of HIV-1 Infection with Early Antiretroviral Therapy Myron S. Cohen, M.D., Ying Q. Chen, Ph.D., Marybeth McCauley, M.P.H., Theresa Gamble, Ph.D., Mina C. Hosseinipour, M.D., Nagalingeswaran Kumarasamy, M.B., B.S., James G. Hakim, M.D., Johnstone Kumwenda, F.R.C.P., Beatriz Grinsztejn, M.D., Jose H.S. Pilotto, M.D., Sheela V. Godbole, M.D., Sanjay Mehendale, M.D., Suwat Chariyalertsak, M.D., Breno R. Santos, M.D., Kenneth H. Mayer, M.D., Irving F. Hoffman, P.A., Susan H. Eshleman, M.D., Estelle Piwowar-Manning, M.T., Lei Wang, Ph.D., Joseph Makhema, F.R.C.P., Lisa A. Mills, M.D., Guy de Bruyn, M.B., B.Ch., Ian Sanne, M.B., B.Ch., Joseph Eron, M.D., Joel Gallant, M.D., Diane Havlir, M.D., Susan Swindells, M.B., B.S., Heather Ribaudo, Ph.D., **Vanessa Elharrar, M.D.**, David Burns, M.D., Taha E. Taha, M.B., B.S., Karin Nielsen-Saines, M.D., David Celentano, Sc.D., Max Essex, D.V.M., and Thomas R. Fleming, Ph.D. for the HPTN 052 Study Team N Engl J Med 2011; 365:493-505 August 11, 2011

Correlates of HIV acquisition in a cohort of Black men who have sex with men in the United States: HIV prevention trials network (HPTN) 061. Koblin BA, Mayer KH, Eshleman SH, Wang L, Mannheimer S, del Rio C, Shoptaw S, Magnus M, Buchbinder S, Wilton L, Liu TY, Cummings V, Piwowar-Manning E, Fields SD, Griffith S, **Elharrar V**, Wheeler D; HPTN 061 Protocol Team. PLoS One. 2013 Jul 26;8(7):e70413. doi: 10.1371/journal.pone.0070413. Print 2013.

Dose Frequency Ranging Pharmacokinetic Study of Tenofovir-Emtricitabine After Directly Observed Dosing in Healthy Volunteers to Establish Adherence Benchmarks (HPTN 066). Hendrix CW, Andrade A, Bumpus NN, Kashuba AD, Marzinke MA, Moore A, Anderson PL, Bushman LR, Fuchs EJ, Wiggins I, Radebaugh C, Prince HA, Bakshi RP, Wang R, Richardson P, Shieh E, McKinstry L, Li X, Donnell D, **Elharrar V**, Mayer KH, Patterson KB. AIDS Res Hum Retroviruses. 2015 Oct 15

Sexual Networks and HIV Risk among Black Men Who Have Sex with Men in 6 U.S. Cities. Tieu HV, Liu TY, Hussen S, Connor M, Wang L, Buchbinder S, Wilton L, Gorbach P, Mayer K, Griffith S, Kelly C, **Elharrar V**, Phillips G, Cummings V, Koblin B, Latkin C; HPTN 061. PLoS One. 2015 Aug 4;10(8):e0134085.

The feasibility of an intensive case management program for injection drug users on antiretroviral therapy in St. Petersburg, Russia. Shaboltas AV, Skochilov RV, Brown LB, **Elharrar VN**, Kozlov AP, Hoffman IF. Harm Reduct J. 2013 Sep 5;10(1):15. [Epub ahead of print]

Elharrar, Vanessa et al. “Guia Operativa: Vigilancia de Deshidratación por Enfermedad Diarreica Aguda y/o Vómitos Causados por Rotavirus, Vigilancia de Invaginación Intestinal en Guatemala.”

Current as of June, 2024

Operative Guide for Rotavirus Surveillance- (Spanish.) Published and distributed by Guatemala's Ministry of Health 12/ 2004

Elharrar, Vanessa et al. "Protocolo para la Vigilancia Hospitalaria de Deshidratación por Enfermedad Diarreica Aguda y/o Vómitos Causados por Rotavirus y para la Invaginación Intestinal en Guatemala" Protocol for Rotavirus Surveillance in Guatemala (Spanish.) Published and distributed by Guatemala's Ministry of Health 11/ 2004

Elharrar, Vanessa et al. "Implementing the World Health Organization's Generic Protocol for Rotaviral Disease Burden Assessment: Guatemala's Experience." PAHO EPI Newsletter May, 2005

Role of Oral Pre-exposure Prophylaxis (PrEP) in Current and Future HIV Prevention Strategies. D. Burns, C. Grossman, J. Turpin, **V. Elharrar**, F. Veronese. Current HIV/AIDS Reports. 05 Oct 2014. doi: **10.1007/s11904-014-0234-8**

ACT2 Peer-Driven Intervention Increases Enrollment into HIV/AIDS Medical Studies Among African Americans/Blacks and Hispanics: A Cluster Randomized Controlled Trial. Marya Gwadz, Charles M Cleland, Mindy Belkin, Amanda Ritchie, Noelle Leonard, Marion Riedel, Angela Banfield, Pablo Colon, **Vanessa Elharrar**, Jonathan Kagan, Donna Mildvan. AIDS Behav. 2014 Jun 25. Epub 2014 Jun 25

Intimacy versus isolation: a qualitative study of sexual practices among sexually active HIV-infected patients in HIV care in Brazil, Thailand, and Zambia. Closson EF; Mimiaga MJ; Sherman SG; Tangmunkongvorakul A; Friedman RK; Limbada M; Moore AT; Srithanaviboonchai K; Alves CA; Roberts S; Oldenburg CE; **Elharrar V**; Mayer KH; Safren SA. *PLoS One*. 2015; 10(3):e0120957 (ISSN: 1932-6203)

Antiretroviral Medication Adherence and Amplified HIV Transmission Risk Among Sexually Active HIV-Infected Individuals in Three Diverse International Settings. Magidson JF, Li X, Mimiaga MJ, Moore AT, Srithanaviboonchai K, Friedman RK, Limbada M, Hughes JP, Cummings V, Gaydos CA, **Elharrar V**, Celentano D, Mayer KH, Safren SA. AIDS Behav. 2015 Aug 6

Abstracts and Presentations"

IAS, Vancouver 2015

Final results of the HPTN 052 randomized controlled trial: antiretroviral therapy prevents HIV transmission

M. Cohen¹, Y. Chen², M. McCauley³, T. Gamble⁴, M. Hosseinipour^{5,6}, N. Kumarasamy⁷, J. Hakim⁸, N. Kumwenda⁹, T. Brum¹⁰, B. Grinsztejn¹¹, S. Godbole¹², S. Chariyaalertsak¹³, B. Riegel Santos¹⁴, K. Mayer^{15,16}, I. Hoffman¹⁷, S. Eshleman¹⁸, E. Piwowar-Manning¹⁸, S.-S. Ou¹⁹, L. Cottle²⁰, J. Makhema²¹, L. Mills²², R. Panchia²³, S. Badal-Faesen²⁴, J. Eron⁵, J. Gallant²⁵, D. Havlir²⁶, S. Swindells²⁷, V. Elharrar²⁸, D. Burns²⁸, T. Taha²⁹, K. Nielsen³⁰, D. Celentano³¹, M. Essex^{32,33}, T. Fleming³⁴, HPTN 052 Study Group

IAS, 2015

HPTN 067/ADAPT study: a comparison of daily and intermittent pre-exposure prophylaxis (PrEP) dosing for HIV prevention in men who have sex with men and transgender women in New York city

S. Mannheimer, Y. Hirsch-Moverman, A. Loquere, J. Franks, J. Hughes, S.-S. Ou, K.R. Amico, C. Hendrix, B.J. Dye, E. Piwowar-Manning, M. Marzinke, V. Elharrar, M. Stirratt, R.M. Grant, HPTN

Current as of June, 2024

IAS, 2015

HPTN 067/ADAPT study: a comparison of daily and non-daily pre-exposure prophylaxis dosing in Thai men who have sex with men, Bangkok, Thailand T.H. Holtz¹, A. Chitwarakorn, M.E. Curlin, J. Hughes, K.R. Amico, C. Hendrix, B.J. Dye, P.L. Anderson, S.-S. Ou, V. Elharrar, S.H. Eshleman, M. Stirratt, R.M. Grant, Bangkok HPTN 067/ADAPT Study Team *1Thailand Ministry of Public Health - U.S. Centers*

IAS, 2015

HPTN 067 ADAPT: 'PrEP Ubuntu' and experiences with open-label PrEP among South African women

M. Wallace¹, L.-G. Bekker, S. Roux, M. Atujuna, E. Sebastian¹, B. Dye, V. Elharrar, R. Grant, R. Amico

CROI, 2015

HPTN 067/ADAPT Cape Town: A Comparison of Daily and Nondaily PrEP Dosing in African Women Linda-Gail Bekker¹ James Hughes, Rivet Amico, Surita Roux, Craig Hendrix, Peter L. Anderson, Bonnie Dye, Vanessa Elharrar, Michael J. Stirratt, Robert Grant

CROI, 2014

Tenofovir-Emtricitabine Directly Observed Dosing: 100% Adherence Concentrations (HPTN 066)

Craig W. Hendrix, Adriana Andrade, Angela D. Kashuba, Mark Marzinke, Peter L. Anderson, Ayana Moore, Vanessa Elharrar, Lei Wang, Kenneth H. Mayer, Kristine B. Patterson

8th International Conference on HIV Treatment and Prevention Adherence, 2013

Perceived Infectiousness and Belief About Treatment as Determinants of ART Use and Adherence among High Risk, HIV-Infected Patients in Chiang Mai, Lusaka, and Rio de Janeiro: Qualitative Results from HPTN 063 Matthew Mimiaga (presenting), Rose Closson, Kenneth Mayer, Ayana T. Moore, Arunrat Tangmunkongvorakul, Kriengkrai Srithanaviboonchai, Ruth Khalili Friedman, Carla Alves, Sarah Roberts, Mohammed Limbada, Vanessa Elharrar, Susan Shurman, Steven A. Safren

8th International Conference on HIV Treatment and Prevention Adherence, 2013

Adherence and HIV "Transmissibility" in High-Risk HIV-Infected Individuals from Diverse Geographic Settings: Baseline Data from HPTN063

Steven A. Safren (presenting), Matthew Mimiaga, Ayana T. Moore, James Hughes, Kriengkrai Srithanaviboonchai, Ruth Khalili Friedman, Mohammed Limbada, Xin Li, Vanessa Cummings, Charlotte Gaydos, Corey Kelly, Vanessa Elharrar, David Celentano, Kenneth Mayer

IAS, 2012

Correlates of HIV incidence among black men who have sex with men in 6 U.S. cities (HPTN 061)

B. Koblin, K. Mayer, S. Eshleman, L. Wang, S. Shoptaw, C. del Rio, S. Buchbinder, M. Magnus, S. Mannheimer, T.-Y. Liu, V. Cummings, E. Piwowar-Manning, S. Fields, S. Griffith, V. Elharrar, D. Wheeler, HPTN 061 Study Team

IAS, 2011

Antiretroviral treatment to prevent the sexual transmission of HIV-1: results from the HPTN 052 multinational randomized controlled trial M. Cohen, Y. Chen, M. McCauley, T. Gamble, R. Bollinger, Y. Bryson, D. Burns, D. Celentano, S. Chariyalertsak, F. Conradie, L. Cottle, G. de Bruyn, V. Elharrar, S. Eshelman, M. Essex, E.C.J. Filho, S. Godbole, B. Grinsztejn, J.G. Hakim, I.F. Hoffman, M.

Hosseinipour, N. Kumarasamy, J. Kumwenda, J. Makhema, A. Martinez, K.H. Mayer, S. Mehendale, L.A. Mills, K.A.-H. Nielsen, J.H.d.S. Pilotto, E. Piwowar-Manning, I. Sanne, B.R. Santos, T. Taha, L. Wang, S. Safren, T. Fleming, HPTN052 Protocol Team

1st Boston /Paris Biotechnology Summit Speaker on Public Funding for Biomedical Research, May 2017

Delivered lecture to the incoming Fogarty Fellows titled “Prevention Science Program” 2013 AND 2014

USCA Community Partners panel member and discussant on injectable PrEP, 2013