RICHA CHANDRA, MD, MBBS, MBA

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KEY POSITIONS

Novartis Pharmaceutical Corporation, East Hanover, NJ (2021 - Present)

- Clinical Development Head, Communicable Diseases, Global Health Development
- Industry representative on FDA's antimicrobial Advisory Committee (2019- 2023)

Novartis Pharmaceutical Corporation, East Hanover, NJ (2015 - 202t)

- Senior Global Program Clinical Head, Infectious Diseases, Global Health Development
- Industry representative on FDA's antimicrobial Advisory Committee (2019- 2023)

Novartis Vaccines and Diagnostics, Cambridge, MA (2013 – 2014)

- Development Cluster Head, Cell Culture Based Influenza Vaccines

Pfizer Inc. Emerging Markets Business Unit, NY, NY (2009 – 2013)

- Global Program Team Head, Malaria & Vaccines (2012 –2013)
- Global Program Team Head, Malaria (2009 – 2012)

Pfizer Global Research & Development, Groton/New London, CT (1999– 2009)

- Global Program Clinical Head, Malaria (2007-2009)
- Global Translational Medicine Head, Infectious Diseases (2003 – 2007)
- Early Clinical Portfolio Leader, Antibacterial Agents (1999 – 2003)

Pfizer (India) Limited, Mumbai (1994 – 1999)

- VP and Head, International Clinical Research, Biometrics & IT support (1997 – 1999)
- Manager, Scientific & Public Affairs (1995 – 1997)
- Medical Advisor, Infectious Diseases, Inflammation, Cardiovascular Diseases (1994 – 1995)

Roussel Uclaf Limited, Mumbai (1993 – 1994)

- Medical Advisor, Infectious Diseases, Inflammation

Seth GS Medical College & KEM Hospital, Mumbai (1987 – 1992)

- Lecturer, Clinical Pharmacology & Therapeutics

KEY CONTRIBUTIONS

Communicable Diseases Development at Novartis (2013 - Present)

<u>Communicable Disease Area Strategy for Global Health</u>

- Contribute to communicable disease and pandemic preparedness strategy for Novartis
- Develop, mentor and lead a team of physicians and scientists with drug development expertise to implement communicable disease area strategy for Global Health

<u>Pandemic preparedness</u>

- Lead clinical development of COVID-19, Pandemic Preparedness and Global Health Emergency Preparedness assets
- Member of Pandemic Preparedness Steering Committee for Novartis
- Member of EFPIA/ VE Bio-preparedness Task Force for HERA
- Member of NIH sponsored TRACE (Tracking Resistance and Coronavirus Evolution) Working Group
- Member of INTREPID Board and Scientific Working Group on Pandemic Preparedness

Neglected Tropical Disease (NTD) Programs

- Contribute to disease area strategy for neglected tropical diseases for Novartis
- Lead development of Target Product Profiles (TPP) and development and execution of clinical development strategies and plans for NTD portfolio (including malaria, Leishmaniasis, Chagas, Cryptosporidiosis, Dengue, Global Health Emergencies) in collaboration with internal and external stakeholders
- At quarterly NTD Decision Board meetings, review projects, advise research teams and participate in decision making by bringing development perspective

Antibacterial Programs

- Led the Global Clinical Team (GCT) for tobramycin inhalational products to develop and implement clinical development strategies for Cystic Fibrosis (CF) and Bronchiectasis (BE) in collaboration with CF foundation, IMI and other external collaborators
- Led a cross-functional team to develop clinical/registration strategies for early clinical development programs for serious infections with high unmet need in collaboration with external stakeholders

Antiviral Programs

- Lead clinical development strategy and execution of COVID-19 development program in collaboration with external partners
- Led telbivudine Hepatitis B clinical development program in adults and children
- Led development of clinical development strategies for research /early development portfolio

Vaccines

- Led development and implementation of clinical development strategies for influenza vaccines

Other key contributions

- As Chair of the internal scientific review committees, advise clinical teams on clinical development plans and study protocols for Global Health portfolio
- As member of the Novartis Scientific Innovation Think Tank, advise Medicine Development Teams on innovative clinical development strategies
- Worked closely with portfolio decision analytics and external collaborators to develop and pilot a new decision analytics tool for portfolio strategy and prioritization
- Led a global interdisciplinary team to develop and implement a career development roadmap for scientists and physicians in Clinical Development
- Mentor and coach physicians and scientists within Novartis through 1:1 coaching and workshops
- Industry representative on the FDA Advisory Committee for antimicrobial agents (Nov 2019-2023)

Infectious Disease Development, Pfizer (2007-2013)

Malaria Program

- Led the development and access strategy for intermittent preventive treatment of malaria in pregnancy (IPTp) in collaboration with external stakeholders including Medicines for Malaria Venture (MMV), London School of Hygiene and Tropical Medicine, global funding agencies, WHO and African governments (regulatory agencies, National Malaria Control and Maternal & Child Health Programs). Finalist for GBC (Global Business Council for HIV, Malaria and TB) Award in 2011.
- Led a Phase 3 clinical development program for IPTp in pregnant women in sub-Saharan Africa,
- Led Phase2/3 development program for treatment of acute uncomplicated malaria in adults and children in sub-Saharan Africa, Asia and Latin America; led capacity building efforts in the region for clinical development

- Collaborated with Biko Center of Bioethics (Johannesburg) for conducting regional workshops for Ethics Committees and potential investigators on conducting research in vulnerable populations
- Served as a core member on ***WHO's*** Malaria in Pregnancy Working Group
- Participated as a core member on ***Gates Foundation*** sponsored ***MalERA*** Consultative Group on Drugs to develop research priorities and Target Product Profiles for antimalarials with focus on malaria elimination
- Represented pharma industry at WHO workshop on research priorities for developing nations
- Through particapation in WHO Global Health Fellow program, trained and mentored physicians and scientists from African, Asian and Latin American regions in clinical development and operational excellence
- Invited as a guest speaker / expert on conducting clinical trials in low and middle income countries

Vaccines

- Partnered with Global Program Teams to develop clinical and registration strategy for antibacterial vaccines in research/ early development with focus on low and middle income countries (2012-2013)

Translational Medicine and Exploratory Development, Pfizer (1999-2007)

- Led translational medicine and early development strategy, planning and execution of antibacterial and antiviral programs up to clinical Proof of Concept
- Led clinical pharmacology program for Zmax through NDA submission and approval
- As a member of the Technical Advisory Committees in Infectious Disease Research and Development, guided project teams in project prioritization, strategy, planning, and decision making

International Clinical Research, Biometrics and IT Operations, Pfizer India (1997 - 1999)

- Established a department of 58 physicians and scientists to participate in global registration trials
- Led the India team to participate in global clinical trials across therapeutic areas/indications: *infectious diseases* (CAP, sinusitis, otitis media, typhoid fever, invasive aspergillosis, candidemia, malaria), *Oncology* (advanced breast cancer) and *Neuroscience* (resistant schizophrenia and manic depressive psychosis)
- Collaborated with Ministry of Health (MoH), Drugs Controller General of India (DCGI's office), Indian Council of Medical Research (ICMR) and academia to develop national GCP Guidelines and Research Ethics Guidelines; and establish the first independent Ethics Committee in India
- In collaboration with Indian Ministry of Science and Technology and with Pfizer global R&D conducted five regional workshops on IPR and pharmaceutical product patents for hundred national research laboratories under the aegis of National Council for Scientific and Industrial Research (CSIR)

Scientific and Public Affairs, Pfizer India (1995 - 1997)

- Corporate spokesperson on R&D and policy issues
- In collaboration with Federation of Indian Chambers of Commerce and Industries (FICCI), led a large nation-wide quantitative/qualitative research on public perception about implementation of pharmaceutical product patents in India
- As part of a 5-member PhRMA delegation, participated in the presentation/ discussions on the new patent bill in the Upper House of the Parliament (Rajya Sabha)

Medical Advisor, Pfizer India (1994 – 1995)

- Provided medical support for anti-infective/ anti-inflammatory portfolio, and led/ co-led medical aspects of pre-launch, launch, post launch activities for azithromycin and prazosin GITS

Medical Advisor, Pfizer India and Roussel Uclaf (1993 - 1994)

- Provided medical support for anti-infective/ anti-inflammatory portfolio, and led medical aspects of pre-launch, launch, post launch activities for cefotaxime and roxithromycin

Lecturer, Clinical Pharmacology and Therapeutics, Seth GS Medical College, Mumbai (1987 - 1992)

- Taught medical (MBBS, MD), nursing, occupational and physical therapy students through lectures, tutorials and bedside clinics

EXTERNAL ORGANIZATION MEMBERSHIP

- Infectious Disease Society of America (IDSA)
- American Association of Tropical Medicine and Hygiene (ASTMH)

EDUCATION

M.B.A.	Rensselaer Polytechnic Institute (RPI) Independent Study: Probabilistic portfolio decision Analysis model for multiple-candidate strategy in anti-infective drug development	**2001-2004**
D.N.B. (Clin. Pharm)	Seth GS Medical College & KEM Hospital, Mumbai	**1990-1992**
M.D.	Pharmacology & Therapeutics Seth GS Medical College & KEM Hospital, Mumbai	**1986-1989**
M.B.B.S.	Bachelor of Medicine & Bachelor of Surgery Lady Hardinge Medical College, New Delhi	**1980-85**

SELECT PUBLICATIONS

- Gandhi P, Chandra R, Schmitt EK, Chen C-W, Samantray S, Venishetty VK, Hughes, D. Global impact of human fascioliasis, Fascioliasis, Book editor: Dalton JP, 2nd edition, 2022. Chapter 14: 461-491.

- Jumani R. Blais J, Tillmann HC, Segal F, Wetty D, Ostermeier, Nuber N, Lakshman J, Aziz, N, Chandra, R, Chen WH, Chappell CL, Diagna TT, Manjunatha UH. Opportunities and challenges in developing a Cryptosporidium Controlled Human Infection Model for testing antiparasitic agents. ACS Infect Dis, 2021, 7, 959-968.

- Nolan T, Chotpitayasunondh T, Capeding MR, Carson S, Senders D, Jaehnig P, de Rooij R. **Chandra R**. Safety and tolerability of a cell culture derived trivalent subunit inactivated influenza vaccine administered to healthy children and adolescents: A Phase III randomized, multicenter, observer-blind study. Vaccine 2016; 34: 230-236.

- Diez-Domingo J, Maurizio M, Lopez JG-S, Zuccotti GI, Villani A, Moreno-Perez D, Hernandez MM, Aldean JA, Mateen AA, Enweonye I, de Rooji R, **Chandra R**. Safety and tolerability of cell culture-derived and egg-derived trivalent influenza vaccines in 3 to < 18-year old children and adolescents at risk of influenza-related complications. Int J Infect Dis 2016; 49: 171-178.

- Krastev Z, Petrova D, Kotzev I, Celen, MK, Mendelson M, **Chandra R**, Pandey P, Hamed K. Telbivudine vs tenofovir in hepatitis B patients: OPTIMA roadmap study. World J Hepatol 2016; 8(32): 1402-1413.

- **Chandra R**, Ansah P, Sagara I, Sie A. Tiono AB, Djimde AA, Zhao Q, Robbins J, Penali, LK, Bernhards O. Comparison of azithromycin plus chloroquine versus artemether-lumefantrine for the treatment of uncomplicated Plasmodium falciparum malaria in children in Africa: a randomized, open-label study. Malaria J. 2015:14:108.

- **Chandra R,** Orazem J, Ubben D, Duparc S, Robbins J, Vandenbroucke P. Creative solutions to extraordinary challenges in clinical trials: a phase III trial of azithromycin and chloroquine fixed-dose combination in pregnant women in Africa [published online ahead of print April 11 2013]. Malar J. 2013;**12(1):**122

- Zhao Q, Purohit V, Cai J, LaBadie R, **Chandra R**. Relative bioavailability of a fixed combination tablet formulation of azithromycin and chloroquine (AZCQ) in healthy adult subjects. J Bioequiv Availab. 2013;5:001-005.

- Knirsch C, **Chandra R**. Preclinical safety and randomized controlled trial mortality data with azithromycin [letter]. N Eng J Med. 2012; 367: 772-775

- **malERA Consultative Group on Drugs**. A research agenda for malaria eradication: drugs. PLoS Med 2011; 8(1): e1000402.

- Curatolo W, Liu P, Johnson B , Hausberger A, Quan E, Vendola T, Vatsaraj N, Foulds G, Vincent J, **Chandra R**. Effect of food on a gastrically degraded drug: azithromycin fast dissolving gelatin capsules and HPMC capsules. Pharmaceutical Res. 2011; 28 (7): 1531-1539.

- Pereira MR, Henrich PP, Sidhu ABS, Johnson D , Hardink J, Deusen JV, Lin J, Gore K, O'Brien C, Wele M, Djimde A, **Chandra R**, Fidock DA. In vivo and in vitro antimalarial properties of azithromycin-chloroquine combinations that include the resistance reversal agent amlodipine. Antimicrob Agents Chemoth 2011; 55 (7): 3115-3124.

- Liu P, Allaudeen H, **Chandra R**, Philips K, Jungnik A, Sharma A. Comparative azithromycin serum and WBC pharmacokinetics of a single-dose extended release microshere formulation and a 3-day regimen of tablet formulation in healthy subjects. Antimicrob Agents Chemoth, 2007; 51 (1): 103-109.

- **Chandra R,** Liu, P, Fisher, J, Xie, C. Labadie, R, Benner, RJ, Benincosa L, Sharma, A. Pharmacokinetics (PK) and Gastrointestinal (GI) Tolerability of a Novel Azithromycin Microsphere (AZ-M) Formulation. Clin Pharmacokinetics 2006; 46 (3): 247-269.

- Jacobs. R, Maples, H., Aranda, J, Espinoza, G., Knirsch, C, **Chandra, R**. Pharmacokinetics of intravenously administered azithromycin in pediatric patients. Pediatric Journal of Infect Dis. 2005: 24(1): 24-39.

- Bachmann K, Jauregui L, **Chandra, R**. Thakker, K. Influence of a 3-day regimen of azithromycin on the disposition kinetics of cyclosporin A in stable renal transplant patients. Pharmacological Research, 2003; 47: 549-554