

# **RICHA CHANDRA, MD, MBBS, MBA**

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## **KEY POSITIONS**

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

- Clinical Development Head, Global Health
- Industry representative on FDA's Antimicrobial Advisory Committee (2019- 2023; 2024 - 2027)

### **Novartis Pharmaceutical Corporation, East Hanover, NJ (2015 - 2021)**

- 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**

### **Global Health Development at Novartis (2013 - Present)**

#### Global Health Disease Area Strategy for Global Health

- Contribute to Global Health Disease Area Strategy for Novartis including the areas of antivirals, pandemic preparedness, malaria, sickle cell disease and neglected tropical diseases.
- Develop, mentor and lead a team of physicians and scientists with drug development expertise to implement Global Health Disease Area strategy for Global Health in a seamless Research-Development-Access continuum,

#### Pandemic Preparedness

- Lead clinical development of therapeutics for 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

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### Global Health Programs

- Contribute to disease area strategy for antivirals, malaria, sickle cell disease and neglected tropical diseases for Novartis
- Lead development of Target Product Profiles (TPP) and development and execution of clinical development strategies and plans for Global Health portfolio (including Malaria, Sickle Cell Disease, Leishmaniasis, Chagas, Cryptosporidiosis, Dengue, Global Health Emergencies and Pandemic Preparedness) in collaboration with internal and external stakeholders
- At quarterly Global Health Disease Area 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, Dengue, antivirals for pandemic preparedness and global health emergencies 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 approve clinical teams on and approve clinical development plans and study protocols for Global Health Portfolio
- As Co-Chair of the Global Health Portfolio Review of Clinical Program execution, ensure timely, efficient and high-quality execution of Global Health Clinical Trial.,
- As member of the Scientific Innovation Think Tank, advise Global Program Teams on innovative clinical development strategies.
- As a member of the internal HYPERCARE Team, advise and guide teams on implementation of efficient clinical development strategies and help remove roadblocks.
- 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

### **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.

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- Led a Phase 3 clinical development program for IPTp in pregnant women in sub-Saharan Africa,
- Led Phase 2/3 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
- Represented pharma industry at WHO workshops on
- Through participation in WHO Global Health Fellow program, trained and mentored several 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**

- Led 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 teams to develop and implement biomarker plans and early development strategies, for antibacterial and antiviral programs up to Phase 2 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 Diseases R&D, 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 nationwide 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

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## 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

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

## SELECT PUBLICATIONS

- **ACTIV-3 /TICO Study Group.** Efficacy and safety of Ensovibep for adults hospitalized with COVID-19: A randomized controlled trial. *Annals of Int. Med.* 2022, 175(9); <https://doi.org/10.7326/M22-150>
- 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, 2<sup>nd</sup> 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, Jaehrig 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.

## **RICHA CHANDRA, MD, MBBS, MBA**

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

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- **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 microsphere 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