S. D. Shroff

5/10/2022

CURRICULUM VITAE

NAME: **Shroff,** *MD, MPH, MBA, FACR , FACP* **Sharukh D.** | **DATE:** 09/MAY/2022

POSITION TITLE: Investigator

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PROFESSIONAL LICENSURE: Commonwealth of Virginia Board of Medicine #0101243735 USA

EDUCATION/TRAINING:

(Include baccalaureate or other initial professional education such as nursing, postdoctoral training, GCP training.)

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Arizona College of Medicine Tucson, Arizona, USA	Fellowship	2015	Integrative Medicine
National Institute of Health, National Institute of Arthritis and Musculoskeletal & Skin Disease Bethesda, Maryland, USA	Fellowship	2005-2007	Rheumatology
Drexel University College of Medicine & Hahnemann University. Philadelphia, PA , USA	Doctor of Medicine	2005	MD
Drexel University College of Medicine Philadelphia, PA,USA	Residency	2003-2005	Internal Medicine
Long Island College Hospital Brooklyn, NY, USA	Internship	2002-2003	Internal Medicine
Johns Hopkins University & Bloomsberg School of Hygiene and Public Health, Baltimore, Maryland, USA	MPH	2002	Public Health
University of New Haven West Haven, Connecticut, USA	MBA	2002	Business Administration
King Edward Memorial Hospital Bombay, India	M.B. B.S.	1996	Bachelor of Medicine & Bachelor of Surgery

Specialization: Rheumatology

POSITIONS AND EMPLOYMENT:

2008-present Rheumatologist, Spectrum Medical, Inc. (formerly Danville Orthopedic Clinic, Inc.), Danville, Virginia, USA
2007-2008 Rheumatology Associate, Arthritis and Osteoporosis Center, Brooklyn, NY, USA
1998-2002 Medical Research Associate, Bayer Corporation, West Haven, CT, USA
1997-1998 Clinical Scientist, Wyeth-Ayerst Labs, St. Davids, PA, USA

BOARD CERTIFICATIONS, OTHER EXPERIENCE, AND PROFESSIONAL MEMBERSHIPS:

2015-present Fellow of the American College of Physicians (FACP)
2012-present Fellow of the American College of Rheumatology(FACR)
2007-present Board Certified in Rheumatology by American Board of Internal Medicine
2005-present Board Certified in Internal Medicine by American Board of Internal Medicine
2001-present American Medical Association

2004-present	American College of Physicians
2006-present	Rheumatism Society of the District of Columbia
2007-present	American College of Rheumatology

Research Education:

2006	Certificate of Training in Principles and Practice of Clinical Research, NIH
2005	Certificate of Training in Ethical and Regulatory Aspects of Clinical Research, NIH
2000	Certificate of Training in the Drug Approval Process, Barnett International
2000	Certificate in Clinical Research from Johns Hopkins School of Hygiene & Public Health
1999	Certificate of Training in Adverse Event Management, Barnett International
1999	Certificate of Training in Clinical Research Writing, Barnett International
1998	Certificate of Training in Clinical Trial Monitoring, Barnett International

Publications/Presentations:

2008	Journal publication: "A pilot study to evaluate the safety and efficacy of the long-acting interleukin-1 inhibitor rilonacept (interleukin-1 Trap) in patients with familial cold autoinflammatory syndrome." Arthritis and Rheumatism . Volume 58 Issue 8. Pages 2432-2442. Published 30Jul2008.
June 2006	Poster Presentation at the NIAMS, NIH Retreat: "Does exogenous IL-1 Receptor antagonist have an effect on weight gain? National Institute of Health, Bethesda, Maryland, USA
June 2006 & May 2007	Poster Presentation at the Fellows Forum (2007) and NIAMS Retreat (2006): "Ocular Manifestations in Patients Neonatal Onset Multisystem Inflammatory Disease (NOMID)". National Institute of Health, Bethesda, Maryland, USA

Clinical Trial Experience:

Prior to completing Doctor of Medicine, worked for Fulford India LTD (affiliate of Schering-Plough Corp. USA) as a Clinical Research Associate from July 1995-July 1996. Then in June 1998-May 2002, worked full-time for Bayer Corporation as a Medical Research Associate. Responsible for all monitoring and site management aspects of clinical trials across therapeutic groups according to FDA regulations; Review of clinical protocols, pre-clinical data, and case report forms. Also conducted pre-investigational, study start-up, periodic monitoring and study close-out visits. Monitored trials with Cardio-Pulmonary and Oncology Disease processes (including hypercholesterolemia, hypertriglyceridemia, CHF, chronic bronchitis, erectile dysfunction and Diabetes, Pancreatic Cancer, Small Lung Cell Cancer).

As a fellow at NIH assisted in conducting clinical trials for many indications such as genetics, Rheumatoid Arthritis, Connective Tissue Disorders, and skin disorders.

Clinical Trials as Investigator:

A Randomized, Double-Blind, Placebo-Controlled **Phase 3** Efficacy Study of an XXX vaccine in the prevention of Lower Respiratory Tract Disease caused by RSV in Adults Aged 60 years and older. (8/2021-Present). Role- Sub Investigator.

A **Phase 2** Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of XXX for the treatment of Moderate to Severely Active Systemic Lupus Erythematosus. (5/2021-2022). Role- Principal Investigator.

A **Phase 2**. Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Subjects with Fibromyalgia. (2/2021-2022) Role- Principal Investigator.

A **Phase 3** Prospective, multicenter, double-blind, randomized, placebo-controlled study to evaluate the efficacy of XXX in patients with osteoarthritis of the knee. 12/2020-Present
Role- Sub-Investigator (Unblinded Injector).

A Phase 3, 14-Day, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Multicenter Study of the Efficacy and Safety of XXX in subjects with pain due to Acute Back Muscle Spasm. (12/2020-11/2021). Role- Sub Investigator.

A Randomized, Double-Blind, Placebo-Controlled, Multi-center Pilot Study of a Single Injection Cross-linked XXX Combined with YYY to Provide Symptomatic Relief of OA of the Knee. (10/2020-2022) Role- Sub-Investigator (Unblinded Injector). **Phase 2**.

Study designed to validate the XXX Lyme Assay using samples from patients clinically diagnosed with Lyme disease and also to compare test results to other standard diagnostic tests.
Role- Principal Investigator.

Phase 2, Randomized, Double-Blind, Placebo Controlled study of the safety and efficacy of XXX for the treatment of adhesive Capsulitis of the Shoulder. (8/2020-2022). Role- Sub-Investigator

A Randomized, Controlled Pragmatic Phase **3B/4** Study of XXX in patients with Rheumatoid Arthritis. (2020-Present). Role: Principal Investigator.

A **Phase 3**, Double-Blind, Multicenter Study to evaluate the Long Term Safety and Efficacy of XXX in Patients With Systemic Lupus Erythematosus (2019-2021). Role: Principal Investigator.

A Phase 3, Randomized, Controlled, Double-Blind Study to evaluate the efficacy and safety of an intra-articular injection of XXX in adults with pain due to severe osteoarthritis of the knee. (2019-2020)
Role: Sub Investigator.

A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to evaluate the Efficacy and Safety of XXX in Patients with Glenohumeral Osteoarthritis or Shoulder Adhesive Capsulitis. (2019-2020) Role: Sub Investigator.

A **Phase 3**, Randomized, Double-Blind, Placebo-Controlled, 2 Injection, 52 Week Study to Evaluate the Efficacy and Safety of Intra-articular injections of XXX in subjects with Chronic, Moderate to Severe osteoarthritis knee pain. (2019-2020) Role: Sub Investigator.

Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 3 Study of **XXX** in Patients With Systemic Lupus Erythematosus. (2018-2021).
Role: Principal Investigator.

A **Phase 3**, randomized, double-blind, placebo controlled study to access the effects of xxx on the occurrence of major cardiovascular events in patients with or high risk for cardiovascular disease who are statin intolerant. Role: Sub Investigator. (2018-Present)

A **Phase 3**, multi-center, multi-national, placebo controlled, randomized, double-blind 26 week study to access the safety and efficacy of XXX in patients with severe hypertriglyceridemia. Role: Sub Investigator. (2018-2019)

Randomized, Double-Blind Placebo Controlled, Parallel-group, Multicenter, Dose-Ranging Study to evaluate the Safety and Efficacy of XXX in Severely Obese Patients with Type 2 Diabetes Mellitus. **Phase 2**. Role: Sub Investigator. (2018-2019)

A **Phase 2/3**, An Integrated Assessment of the Safety and Effectiveness of XXX for the Management of Essential Hypertension. Role: Sub Investigator. (Nov 2017-2018)

Device Study- Randomized , Multicenter, Open-Label, Parallel Group Study in Postmenopausal Women with Osteoporosis to evaluate non-inferiority of subject administered XXX vs healthcare provider administered XXX via PFS (2018-2019).
Role: Principal Investigator.

Phase 3, Randomized Withdrawal Double Blind Study of XXXX Monotherapy Compared to XXXX Monotherapy for Maintenance of Remission in Subjects With Rheumatoid Arthritis. (2015-2018).
Role: Principal Investigator.

A **Phase 3**, Multi-Center Double-Blind, Randomized Controlled Study of XXXX and XXXX in Combination or as Monotherapy in Subjects with Psoriatic Arthritis. (2015-2017).
Role: Principal Investigator.

A **Phase 3B**, Randomized, Double-Blind Clinical Trial to Evaluate the Efficacy and Safety of XXXX SC in Combination with XXXX Compared to XXX Monotherapy in Achieving Clinical Remission in Adults with Early Rheumatoid Arthritis who are XXXX Naïve. (2015-2018).
Role: Principal Investigator.

Efficacy, Safety, and immunogenicity of XXX vs YYY in patients with active rheumatoid arthritis: a randomized double blind, parallel arm, multiple dose, active comparator trial. (2015-2018) Ongoing Ext Study.). **Phase 3**.Role: Principal Investigator.

A Randomized, Double-Blind, Placebo Controlled **Phase 3** Study to Evaluate the Efficacy, Safety and Effect on Radiographic Progression of XXX in Subjects with Psoriatic Arthritis. (Feb 2014-2015). Role: Principal Investigator.

A Phase IIb, Multi-center, Randomized, Double-Blind, Placebo Controlled, Multidose, 24 Week Study to Evaluate the Efficacy and Safety of XXX in Subjects with Systemic Lupus Erythematosus (SLE). **Phase 2b**. Role: Principal Investigator (Dec 2013-2015).

Randomized, Double-Blind, Placebo Controlled, Parallel-Group, Multicenter, Worldwide, Proof of Concept Clinical Trial to Evaluate the Safety, Tolerability, and Efficacy of XXX in Subjects with Active Rheumatoid Arthritis and Inadequate Response or Intolerance to Anti-TNF Therapy. (May 2013-October 2013). Role: Principal Investigator

A 5 Year Prospective Observational Registry to Assess Adverse Events of Interest and Effectiveness in Adults with Active, Autoantibody-Positive Systemic Lupus Erythematosus Treated with or Without XXX (2013-Present). Role: Principal Investigator

A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX in Patients with Moderate to Severe Rheumatoid Arthritis (RA) who had an Inadequate Response to one or more TNF-a Inhibitors.
Phase 3b (2012-2013). Role: Principal Investigator

A Phase 3B, Multicenter , Open Label Study to evaluate the Long Term Safety and Efficacy of Subcutaneous XXX in Patients with Systemic Lupus Erythematosus (SLE)
Phase 3b. (4/2012-2015). Role: Principal Investigator.

A Multicenter Randomized, Double-Blind, Placebo Controlled Study to evaluate the Efficacy and Safety of Subcutaneous XXX in Patients with Systemic Lupus Erythematosus (SLE)
Phase 3. (3/2011-2015). Role: Principal Investigator.

A Randomized, Double-Blind, Multicenter, Placebo Controlled, Combination Study to Evaluate the Efficacy and Safety of XXX and YYY compared to YYY Alone in Lowering Serum Uric Acid and Resolving Tophi in Subjects with Tophaceous Gout.(March 2012- 2015). **Phase 3**. Role- Sub-Investigator

A Randomized, Double-Blind, Multicenter, Placebo Controlled, Combination Study to Evaluate the Efficacy and Safety of XXX and YYY compared to YYY Alone in Subjects with Gout who had an inadequate hypouricemic response to Standard of Care YYY.(March 2012- September 2014). **Phase 3.** Role- Sub-Investigator

A Randomized, double Blind, active controlled study of XXX prefilled syringes or XXX reconstituted lyophilizate or YYY for treating acute gouty arthritis flares in frequently flaring patients. **Phase 3**. (5/2011- 2013). Role: Sub Investigator

A Multicenter, Randomized, Double-Blind, Phase 2 Study to Evaluate the Effect of XXX vs placebo on Renal Function in Gout Subjects with Hyperuricemia and Moderate to Severe Renal Impairment. (4/2011-2012). Role: Sub Investigator

A Multicenter, Randomized, Active Control, Phase 3B Study to Evaluate the Cardiovascular Safety of XXX and YYY in Subjects with Gout and cardiovascular Co-morbidities. **Phase 3B.** (3/2011-2016). Role: Sub-Investigator

A Randomized, Multi-Center, Double Blind, Factorial, Comparator and Placebo-Controlled **Phase III** Trial to Evaluate the Efficacy, Tolerability, and Safety of XXX in the treatment of ankle sprains. (2010-2011). Role: Sub-Investigator.

A Randomized, Multi-Center, Double Blind, Placebo-Controlled Phase III Trial to Evaluate the Efficacy, Tolerability, and Safety of XXX in the treatment of Tendonitis and Bursitis of the Shoulder. (2010-2011). Role: Sub-Investigator

An Open Label Extension study of XXX on the treatment and prevention of gout flares in patients with frequent gout flares for whom NSAIDS and/or colchicine are contraindicated, not tolerated or ineffective. (2010-2013). Role: Sub-Investigator

A Randomized, Controlled extension of XXX on the treatment and prevention of gout flares in patients with frequent flares for whom NSAIDS and/or colchicine are contraindicated, not tolerated or ineffective. (2010-Jan. 2011). Role: Sub-Investigator

Phase III, Randomized, controlled study of XXX on the treatment and prevention of gout flares in patients with frequent flares for whom NSAIDS and/or colchicine are contraindicated, not tolerated or ineffective. (2010-2010). Role: Sub-Investigator

A Randomized, Multicenter, Double-Blind, Placebo controlled study to evaluate the Efficacy and Safety of XXX in the treatment of pain associated with mild to moderate ankle sprain. **Phase III.** (2009-2010). Role: Sub-Investigator

Phase III, randomized, double-blind, placebo-controlled, multicenter study evaluating the efficacy of retreatment with xxx in subjects with active rheumatoid arthritis (RA) who are receiving Methotrexate (MTX). (SUNRISE Study/ Sponsor: Genentech).

Phase III, Randomized, Double-Blind, Parallel Group, International Study to Evaluate the Safety and Efficacy of xxx in Combination With xxx Compared to xxx Alone in Methotrexate- Naïve Patients With Active Rheumatoid (FILM Study/Sponsor: Genentech)

Phase III, Randomized, Double-Blind, Parallel Group, International Study to Evaluate the Safety and Efficacy of xxx Compared to Placebo in Patients With Active Rheumatoid Arthritis Who Have an Inadequate Response to at Least One Anti-TNF-α Therapy. (SCRIPT Study/ Sponsor: Genentech)

Phase IV, A Randomized, Double Blind, Parallel-Group Study of Cardiovascular Safety in Osteoarthritis or Rheumatoid Arthritis Patients with or at High Risk for Cardiovascular Disease Comparing XXX with YYY and ZZZ.(PRECISION Study/Sponsor: Pfizer)

Phase III, randomized, double-blind, placebo-controlled, parallel group, multicenter international study designed to evaluate the safety and efficacy profile of xxx in combination with a stable dose of xxx compared to xxx alone, in methotrexate-naïve patients with active rheumatoid arthritis. (IMAGE Study/Sponsor: Genentech).

A randomized, double-blind, parallel group study of the safety and prevention of structural joint damage during treatment with xxx versus placebo, in combination with methotrexate, in patients with moderate to severe active rheumatoid arthritis.(Sponsor: Genentech).

Virginia Department of Health Professions
License Lookup

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License Information

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Name	Sharukh D Shroff
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License Status	Current Active
Additional Public Information*	No

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