Monica E. Luchi

MD, FACR, MBA

The BRACKEN GROUP

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EDUCATION

BACHELOR OF SCIENCE
University of Maryland, Baltimore Co. Campus.
Biology, Health Sciences Policy
1981

MD
Northeastern Ohio Universities, College of Medicine
1987

MBA
George Washington University
2010

Innovation and Entrepreneurship Program
Stanford University
2019

POSTGRADUATE TRAINING & FELLOWSHIP APPOINTMENTS

St. Luke's/ Roosevelt Hospital Center – 1987-1991

Fellow in Rheumatology, University of Pennsylvania School of Medicine – 1992 - 1994

PROFESSIONAL SUMMARY

Creative, innovative, and high-energy executive with broad based large pharma and small biotech experience across early and later stages of development, in multiple therapeutic areas including immunology, dermatology, oncology and immuno-oncology, currently working in the area of pain management. Passionate and experienced, providing hands-on leadership in the development and implementation of innovative clinical programs, together with cross-functional teams, seamless internal partnering with Medical Affairs and Commercial colleagues, and external collaboration with strategic business partners. With deep experience in evidence-based medicine, capitalizing on Key Opinion Leader relationship development and engagement of goal oriented Medical Advisory Boards, collaborations with investigators in the conduct of Investigator Initiated Trials and in the pursuit of creating quality publications. As a member of Senior Executive teams, engaged in defining the direction of the organization and overall global business strategy.

PROFESSIONAL EXPERIENCE

2020 - Present
The Bracken Group
Partner

Apr 2019 – Oct 2020
Sorrento Therapeutics
SVP, Clinical Research and Development

- *Reporting to Business Unit Head*
- *Leading role for primary asset in pain franchise, resiniferatoxin (RTX) being evaluated in pain associated with cancer, osteoarthritis, and other painful conditions*
- *Partnered with Pre-clinical and Regulatory as Medical Lead to submit multiple INDs*
  Pain division
  Coronavirus Treatment Acceleration Program (CTAP)
- *Developed CDP template for the company*
- *Piloted first project CDP for RTX, creating proposed development plan, identifying new indications for future exploration*
- *Created project CDP for RTX, identifying go/no go criteria and proposal for new indications for future exploration*
- *Tasked with development of CDP for 2 additional assets and identifying and defining PoC for those assets*

Nov 2017 – Mar 2019
Celularity Inc.
SVP, Clinical Research and Development

- *Reporting to CMO*
- *Leading* Clinical *Development/Operations and Regulatory teams in transition from Celgene during the 8 months after spin-off*
- *Provided oversight and served as Medical Monitor for ongoing studies of placental natural killer cellular therapeutic in Multiple Myeloma and AML, and also placental adherent cellular therapeutic (MSC-like) in Diabetic Foot Ulcer and Diabetic Peripheral Neuropathy, assuring full transition of all ongoing activities from Celgene to Celularity,*
- *Provided oversight for identification and incorporation of vendor to establish in house clinical safety database; hired and transitioned task to new lead for Safety, overseeing implementation of tasks*

LECTURES

A list is available upon request; topics covered have been primarily Rheumatoid Arthritis, Osteoarthritis, Osteoporosis, and general Rheumatology.

LICENSURE

1989 New York #178398

1992 Pennsylvania #MD046821L

1994 New Jersey #MA061447

SPECIALTY CERTIFICATIONS

1991 Diplomat, Internal Medicine, ABIM

1994 Diplomat, Internal Medicine – Rheumatology, ABIM, Re-Certified, 2007

1998 International Society of Clinical Densitometry

BOARD OF DIRECTOR POSITIONS

Healthcare Business Women's Association (HBA), Leader, Metro Chapter – 2013 -2015

Children's Village NYC, Secretary; member of HR Committee and CEO Compensation Committee– April 2017 - Present

PROFESSIONAL SOCIETIES

American College of Rheumatology

American Society for Bone and Mineral Research

American Society of Clinical Oncology

Women In Bio

Chief, NYC Network for Powerful Women in Marketing and Media

LANGUAGES

Limited German

Limited Spanish

PROFESSIONAL EXPERIENCE

- *Led cross functional team planning towards regulatory request for an accelerated approval path for a cell based therapeutic, including leading efforts with an external registry body to enhance data package*
- *Work together with CMO in identifying opportunities for future product life cycle management; and direction of early development*
- *Initiated a program for cellular therapeutics in the field of longevity, an initial proof of concept study in Parkinson's Disease*
- *Accountable for Biometrics including Statistics, Data Management and Programming*
- *Provided medical support in preparation of Briefing Book and type C regulatory CMC meeting with FDA, with a successful outcome*
- *Supervised Regulatory efforts, including submission of RMAT and 361 designation requests*

Nov 2015 – Jun 2017

Immune Pharmaceuticals

President, Chief Medical Officer

- *Reporting to Interim-CEO after resignation of CEO, promoted to President, with broad oversight and continuing with established responsibilities*
- *Worked together with Finance/BOD in corporate restructuring during a period of recapitalization*
- *Reformulating corporate strategy with Interim-CEO*
- *Continuing to provide leadership as listed below, with focus on clinical development planning, scale up of manufacturing, completion of ongoing clinical studies and future partnering to assure financial stability through investor or pharma partner with established infra-structure and financial assets in place to move the bertilimumab and nano cyclosporine programs forward*

Chief Medical Officer, EVP Global Clinical Development

- *Reporting to Chief Executive Officer*
- *Developed and implemented strategic goals for the organization in terms of both project planning and development partnering goals, in parallel programs which were small molecule pre-clinical/large molecule phase 2/small molecule phase 3*
- *Identified opportunities for collaboration with external experts and companies in both pharma and academic entities, as well as collaborations with patient advocacy groups in relevant therapeutic areas*
- *Developed and provided oversight of implementation of pre-clinical strategy and associated activities, including pre-clinical studies for a topical dermatology asset, studies to support product modification for a biologic, both to satisfy regulatory requirements*
- *Actively engaged in business development and financing opportunities including presentation of clinical capabilities to potential investors and potential partners, including hedge funds/VCs/Family offices/large pharma/biotech*
- *Actively engaged regulatory authorities in collaborative efforts to assure alignment of study designs and development plans*
- *Provided oversight for manufacturing, from current research and pre-clinical needs through scale up to clinical and forecasted commercial needs*
- *Provided oversight for cross-indication medical support and safety reporting*

HONORS AND AWARDS

2000	Listed in Philadelphia Magazine under "Top Docs" for Osteoporosis
2003	Novartis Business Excellence Award for Webcast Investigator's Meeting
2003	Novartis Business Excellence Award for Work in NDA Submission for Paget's Disease
2010	Member of Cambridge Who's Who