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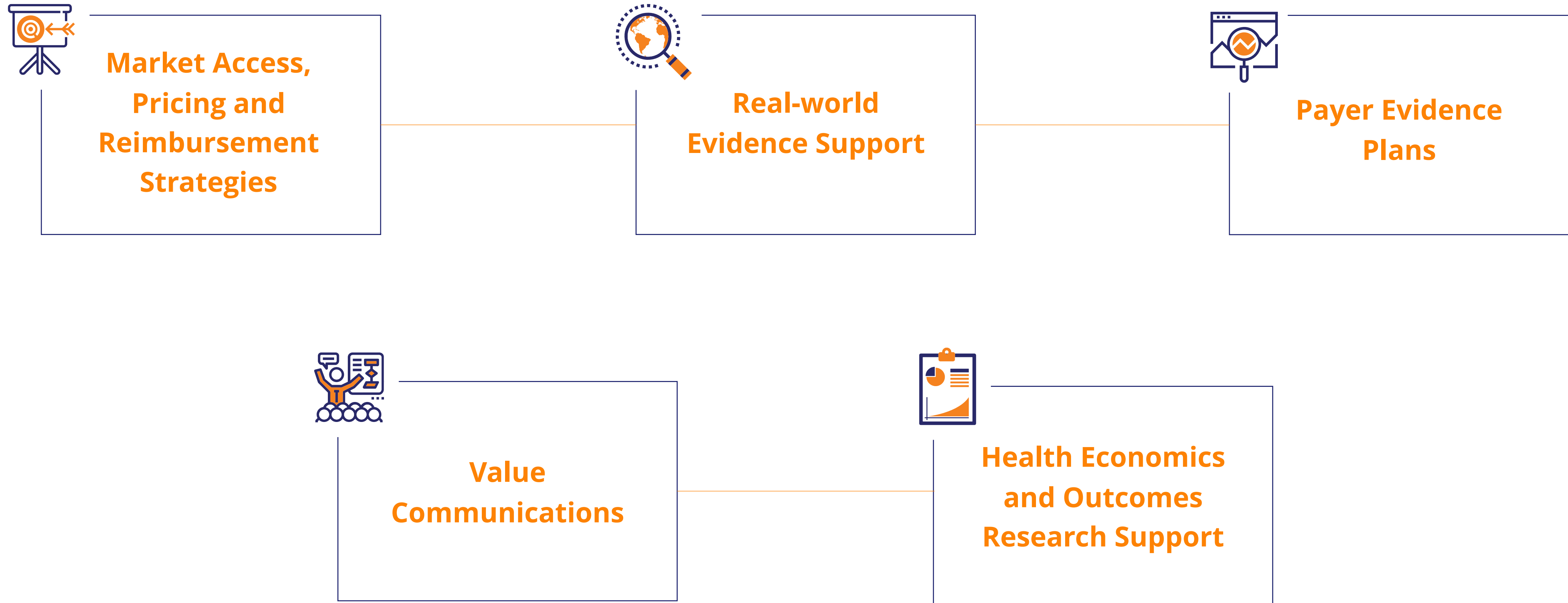
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Section 1

Our Services



Alira Health Clinical for Oncology Services and Experience

Clinical excellence, with a human touch. The Alira Health clinical team delivers clinical excellence from the high-level approach to the hands-on management of every aspect of your trial.



Our Expertise

- ✓ **>100 510(k)s** submitted & cleared
- ✓ **>100 regulatory strategies** for a wide variety of therapeutic areas
- ✓ **>5 PMA and NDAs** submitted & approved



Recent Oncology Projects

PROJECT #1

Full-service trial design and execution for a large, Phase 3 international oncology clinical trial in solid tumors.

PROJECT #2

Full-service Phase 1 trial design and management for a novel oncology immunotherapy drug for the treatment of solid tumors.

PROJECT #3

Study design, site identification, and data management services for a 30-site EU Phase 2 oncology trial.



>7,500
Subjects enrolled



>200
Clinical Studies



15
Countries

Senior Team



Ahmad Bechara,
PhD
*Vice President,
Global Market Access*

Over sixteen years of experience in both the pharmaceutical industry and academic research



Daniel Muscionico,
PharmD, MPH, MBA
*Senior Vice President
EU Operations*

Over twenty years of experience with prior roles as Chief Operating Officer at a global regulatory life sciences consulting firm targeted towards biotech, MedTech, and pharma ventures



James Milnes
PhD
Associate Director

Over twelve years of experience in drug discovery and development in the biotechnology industry, planning and executing research and development projects across a variety of therapeutic areas and three years in consulting



Richard Charter
MIHMEP
*Vice President, MedTech Market
Access, Europe & Asia-pacific*

Over fifteen years of experience in both financial and health economics, with a singular and comprehensive focus on the MedTech market access space.



Jean-François Ricci,
PharmD PhD
*Executive Vice-President
Global Market Access*

Over twenty years of experience in the US and Global HEOR access and commercial roles in pharma and consulting



Isabella Sormani,
MSc, MIHMEP
Associate Director

Over five years of experience in the pharmaceutical industry and consulting



Deepak Sahu
MBA
Manager

More than five years of strategy consulting and project management experience with engagements in Japan, the U.S. and Europe



Catia Proenca,
PhD
Associate Director

Thirteen years of experience in both industry and academic research, with previous roles in Real-World Evidence within the cardio-metabolic franchise in large pharma

Our Team - Chief Medical Officer



Giacomo Basadonna MD, PhD, FACS Chief Medical Officer

Dr. Basadonna, a renowned transplant surgeon, a member of 23 national committees, three hospital committees and 14 professional societies. He has designed and obtained 16 grants, also from large companies and government departments. His previous hospital appointments included UC Davis Medical Center, Yale New Haven Hospital, and UMass Memorial Hospital. Giacomo has presented at major conferences and on TV appearances over 80 times. His multiple publications include over 80 abstracts, 13 limited dissertations, and over 80 publications in peer review journals.

✉ giacomo.basadonna@alirahealth.com

Education

1993 | Ph.D., University of Milan, Milan, Italy
1982 | M.D., University of Milan, Milan, Italy

Post-Graduate Activities

1991 – 1992 | Clinical Fellow in Transplantation Immunology, University of Minnesota, Minneapolis, MN
1990 | Ph.D. in General Surgery, University of Milan, Milan, Italy
1986 – 1990 | Clinical Surgical Resident, University of Milan, Milan, Italy
1983 – 1986 | Research Fellow, University of Texas, Houston, TX
1982 – 1987 | Graduate, School of Endocrine Surgery, University of Milan, Milan, Italy
1982 – 1983 | Research Fellow, Stanford University, Stanford, CA
1981 – 1982 | Internship in Surgery University of Milan Policlinico Hospital, Milan Italy

Academic Activities

Since 2006 | Professor of Surgery (with tenure) - University of Massachusetts
2002 – 2006 | Professor of Surgery - Director of Organ Transplantation - University of Massachusetts
2000 – 2002 | Professor of Surgery - Chief, Pancreas and Islet Transplantation Services - Yale University
1994 – 2000 | Associate Professor of Surgery - Chief, Pancreas Transplantation Services - Yale University
1992 – 1994 | Assistant Professor - Chief, Pancreas Transplantation - U.C. Davis Medical Center
1990 | Associate Director - Pancreas Transplantation Service and Instructor of Surgery - University of Milan, Milan, Italy

Our Team - Senior Leadership



Beth Rayworth
Vice President, Clinical Operations

Beth Rayworth is the VP of Clinical Operations of Alira Health Clinical. Beth ensures Alira Health Clinical's success with her dedication to providing services with the highest standards of quality and ability to see the big picture when it comes to sponsor and study management without losing sight of all the critical details necessary to effectively manage all aspects of each study. Beth has more than 18 years of experience in clinical research across a wide variety of indications and roles, including data management and health economics & outcomes research. She has profound experience in the design and optimization of more than 20 clinical trials. Before her time at Alira Health, Beth worked as the Associate Director and Project Manager at Clinical Assistance Programs (CAP) with a focus pharmaceutical clinical trials.

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Chris Rao
Vice President, Clinical Development

Christopher Rao, CCRP, is the Vice President of Clinical Development of Alira Health Clinical. Chris has over 12 years of experience in clinical research, with proficiency in a wide range of indications including oncology, supportive care, medical devices, and dermatology. Chris plays a leading role in overlooking Alira Health Clinical's day to day operations. With his experience in project management, study design and monitoring, regulatory matters, and data quality management, Chris works closely with executive management and mentors of the Alira Health Clinical team. Chris has previously served as a Project Manager at Clinical Assistance Programs (CAP). Prior to joining CAP, Chris worked as an analyst at Stone-Crowne Associates, performing pharmaceutical marketing data analysis for clients such as Johnson & Johnson as well as financial analysis for MIT and Harvard University.

✉ chris.rao@alirahealth.com



Mary McNamara-Cullinane
Senior Vice President, Regulatory Affairs

Mary McNamara-Cullinane has over 25 years of regulatory experience in the medical device, diagnostics and biotech industries. She has successfully authored over 170 510(k)s, multiple PMAs, two De Novo submissions and has been responsible for several clinical trials. In addition, she has strong knowledge of global regulatory practices and registrations in Europe, Korea, and Australia having worked on many technical files and CERs. Most recently, Mary was responsible for US regulatory strategy at Intrinsic Therapeutics, VP of Regulatory and Clinical Affairs at Echo Therapeutics, Director of Regulatory Affairs at Z-Medica, and Director of Regulatory Affairs and Quality Assurance at Molecular Biometrics. Prior to Molecular Biometrics, Mary was in regulatory consulting for 17 years at Medical Device Consultants, Inc.

✉ mary.mcnamara@alirahealth.com

Some Past References

Selected Track Record

