



COMMUNICATING IN CLINICAL TRANSLATION:

HOW A SMALL RESEARCH INSTITUTE IN VAIL BECAME A GLOBAL LEADER IN REGENERATIVE MEDICINE RESEARCH

From the laboratory bench to patient care, SPRI epitomizes the bench-to-bedside research model

Since its founding in 1988, Steadman Philippon Research Institute (SPRI) has been on the forefront of orthopaedic and sports medicine research. Founder Dr. J. Richard Steadman, a pioneer of orthopaedic surgery techniques and an original proponent of harnessing the body's innate healing response, launched what has become one of the largest and most robust orthopaedic outcomes databases in the world. This database, which now tracks more than 45,000 patient surgeries, has led to the validation of many revolutionary procedures, which are now the standard of care across orthopaedic and sports medicine practices worldwide.

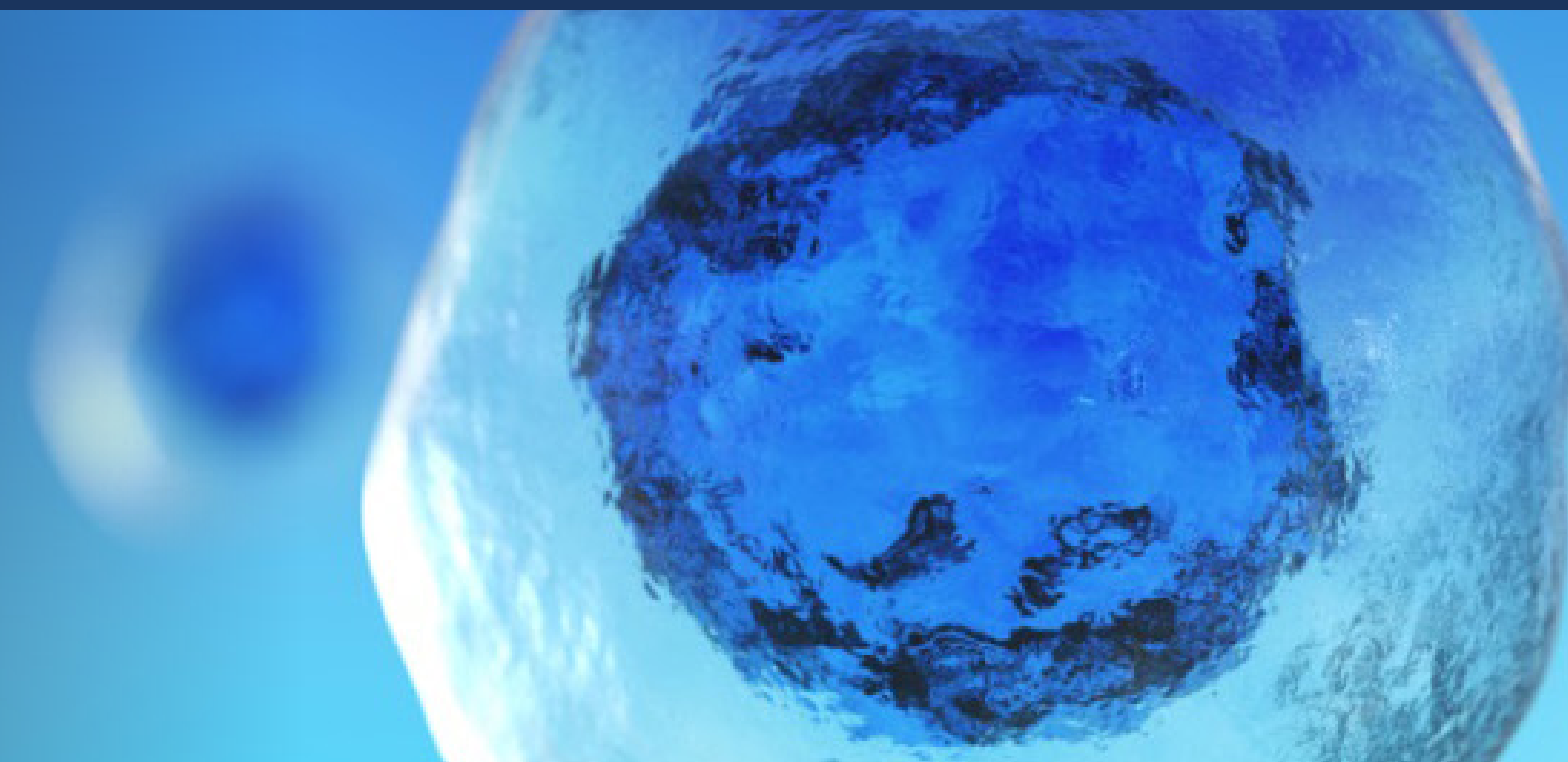
TWO ORGANIZATIONS CONNECTED BY INNOVATION

SPRI shares a symbiotic relationship with The Steadman Clinic, a world-renowned orthopaedic and sports medicine practice that is a leader in innovative treatments, techniques and best-in-class patient care. The two organizations work closely—discoveries made at SPRI are translated clinically, and the innovative research conducted at SPRI is enhanced by the patient data compiled at The Steadman Clinic. Led by SPRI Chair and The Steadman Clinic Managing Partner Dr. Marc J. Philippon, The Steadman Clinic also partners closely with SPRI in its federally funded clinical trials, translating biologic therapies and innovative therapeutics to patients. There are currently six clinical trials underway—supported by the National Institutes of Health (NIH) and Department of Defense (DoD)—that integrate SPRI's cutting-edge research with the world-class orthopaedic care of The Steadman Clinic.

SYNERGY IS THE DIFFERENTIATOR

If you asked SPRI's scientists what made SPRI special, you'd quickly hear about The Steadman Clinic. And if you asked The Steadman Clinic physicians about what made the practice unique, you'd hear about SPRI. SPRI's Chief Scientific Officer Dr. Johnny Huard shared that in over 20 years of working within a university system, he worked on 3 clinical trials. "And in the past three years at SPRI, we're working on 6 trials supported by federal agencies—it's because of the true connectivity and partnership between the physicians and scientists. The level of collaboration and synergy between these organizations is simply unheard of in other spaces."

A Distinctive Award for an Innovative Organization



IN JULY 2020, SPRI LEARNED THAT IT HAD BEEN AWARDED THE PRESTIGIOUS REGENERATIVE MEDICINE INNOVATION PROJECT (RMIP) FROM THE NATIONAL INSTITUTES OF HEALTH (NIH). THIS AWARD IS A FIVE-YEAR CLINICAL TRIAL WITH A 1:1 STRUCTURE—HALF OF THE TOTAL \$6 MILLION AWARD IS FUNDED BY THE NIH, AND THE REMAINING \$3 MILLION IS FUNDED BY PHILANTHROPIC MATCHES. AS AN ORGANIZATION THAT HAS LONG PRIDED ITSELF ON BEING POWERED BY PHILANTHROPY, THE RMIP IS A NATURAL FIT FOR SPRI.

THE RMIP IN DETAIL

“The Use of Senolytic and Anti-Fibrotic Agents to Improve the Beneficial Effect of Bone Marrow Stem Cells for Osteoarthritis” is designed to treat patients with senolytic agents prior to extracting bone marrow stem cells to eliminate pre-existing senescent cells in the body. The goal of this trial is to determine if the use of Fisetin and/or Losartan improves the benefit of Bone Marrow Stem Cell Treatment in patients experiencing osteoarthritis in the knee.

The study will include a total of 100 patients who will participate as follows:

- **25 patients** will receive Bone Marrow Stem Cell Treatment and a Placebo
- **25 patients** will receive Bone Marrow Stem Cell Treatment and Losartan (anti-fibrotic medication)
- **25 patients** will receive Bone Marrow Stem Cell Treatment and Fisetin (senolytic supplement)
- **25 patients** will receive Bone Marrow Stem Cell Treatment, Losartan and Fisetin

ONE OF THE DIFFERENTIATING ELEMENTS OF SPRI'S APPROACH TO RESEARCH IS THE INVOLVEMENT OF EACH SCIENTIFIC DEPARTMENT ALONGSIDE THE CLINICAL TEAMS FROM THE STEADMAN CLINIC.

SPRI is currently ahead of its recruitment schedule for the project. Eighty-two patients have been recruited for the trial, with over 150 people on the waiting list to participate. The excitement over the project indicates that this research is timely, and patients with knee osteoarthritis are looking for new treatment options to improve their physical health. SPRI is hopeful that additional philanthropic funding for this research will enable the team to enroll more interested participants.

NEW AWARDS FOR SPRI'S RMIP

In addition to recruitment progress in the clinical trial, SPRI has received added success in the first two years of the project. The NIH issued two new awards for the project: 1) a supplemental award to allow SPRI to further explore peripheral blood, bone marrow and synovial fluid in the regenerative medicine lab and 2) an award for Year 2 (of the trial) in recognition of SPRI achieving its milestones.

With SPRI's early success in the RMIP, the NIH created an Innovation Catalyst that includes the University of Maryland and Georgia Tech to conduct additional assays on the human

specimens collected as part of the RMIP, at no cost to SPRI. The Catalyst will conduct assays like mRNA single sequencing and Proteomics, utilizing equipment that SPRI does not have in its regenerative medicine lab. Access to these technologies will position SPRI for future funding opportunities.

TEAM SCIENCE MAKES THE TRIAL UNIQUE

One of the differentiating elements of SPRI's approach to research is the involvement of each scientific department alongside the clinical teams from The Steadman Clinic. While the RMIP utilizes regenerative medicine and clinical medicine at its core, the trial is enhanced by its biomechanics testing, advanced imaging and SPRI's unique outcomes database. The result of this technique is a multifaceted approach to research, where patients engage in a comprehensive program, bolstering SPRI's findings.

SPRI employs this multipronged approach in each of its clinical trials, which distinguishes the institute from other research centers.

SPRI TO OPEN NEW LABORATORY IN BASALT, COLORADO

The Steadman Clinic's newest location is opening on April 4, 2022 in Basalt, Colorado—20 miles from Aspen. Emblematic of SPRI and The Steadman Clinic's symbiotic relationship, the new clinic will include a SPRI regenerative medicine laboratory located within the clinic space. A large glass window will allow patients and visitors to see into the laboratory, watching SPRI's cutting-edge science as it happens.



GROWING SPRI'S CLINICAL TRIALS

A major focus of SPRI's Basalt laboratory will be expanding its clinical trials to the region. Participants from Aspen and the Roaring Fork Valley will be able to participate in some of SPRI's federally funded clinical trials, broadening the reach of the research. This includes a Department of Defense (DoD)-funded trial involving femoroacetabular impingement (FAI) and labral tears of the hip, led by SPRI Chair and The Steadman Clinic Managing Partner Dr. Marc Philippon and Dr. Johnny Huard. This trial will have patient representation from both the new lab in Basalt and SPRI in Vail. In addition to clinical trials, the SPRI Basalt lab will also analyze patient samples as part of the organization's Healthy Aging Program. Previously, patients from Aspen and the Roaring Fork Valley would need to travel to Vail to participate in SPRI's research; the new Basalt laboratory will enable these individuals to engage in SPRI's research within their own community.

The Basalt facility includes an ambulatory surgery center and rehabilitation services alongside The Steadman Clinic and SPRI. The building is a partnership with The Steadman Clinic, Orthopedic Care Partners, Aspen Valley Hospital and Vail Health.

