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Steadman Philippon Research Institute
Building & Leading a Successful Research Organization

HCCA Research Compliance Conference

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THE STEADMAN CLINIC AND **STEADMAN PHILIPPON** RESEARCH INSTITUTE

U.S. OLYMPIC & PARALYMPIC NATIONAL MEDICAL CENTER

SESSION OVERVIEW

1. Getting Started: What needs to be in place and how do you accomplish it?
2. Setting Goals: Where do you want to be and how do you plan to get there?
3. Continuous Execution and Improvement: How do you measure, maintain and celebrate success?

Academic
Non-Profit
Industry: *LGVN NASDAQ*

Building on our legacy of excellence in orthopaedic sports medicine, SPRI is unlocking the secrets of healing, finding cures and enhancing lives through global leadership in regenerative medicine, scientific research, innovation and education.

"What sets us apart is the way we can quickly transfer the exciting research being done at SPRI to our patients at The Steadman Clinic." - Dr. Marc Philippon

22-plus physicians
Locations in Vail, Aspen, Basalt and Frisco, CO
60 research staff
Regenerative medicine, robotics, surgical skills and biomotion laboratories
Extensive outcomes database
NIH and DoD funded
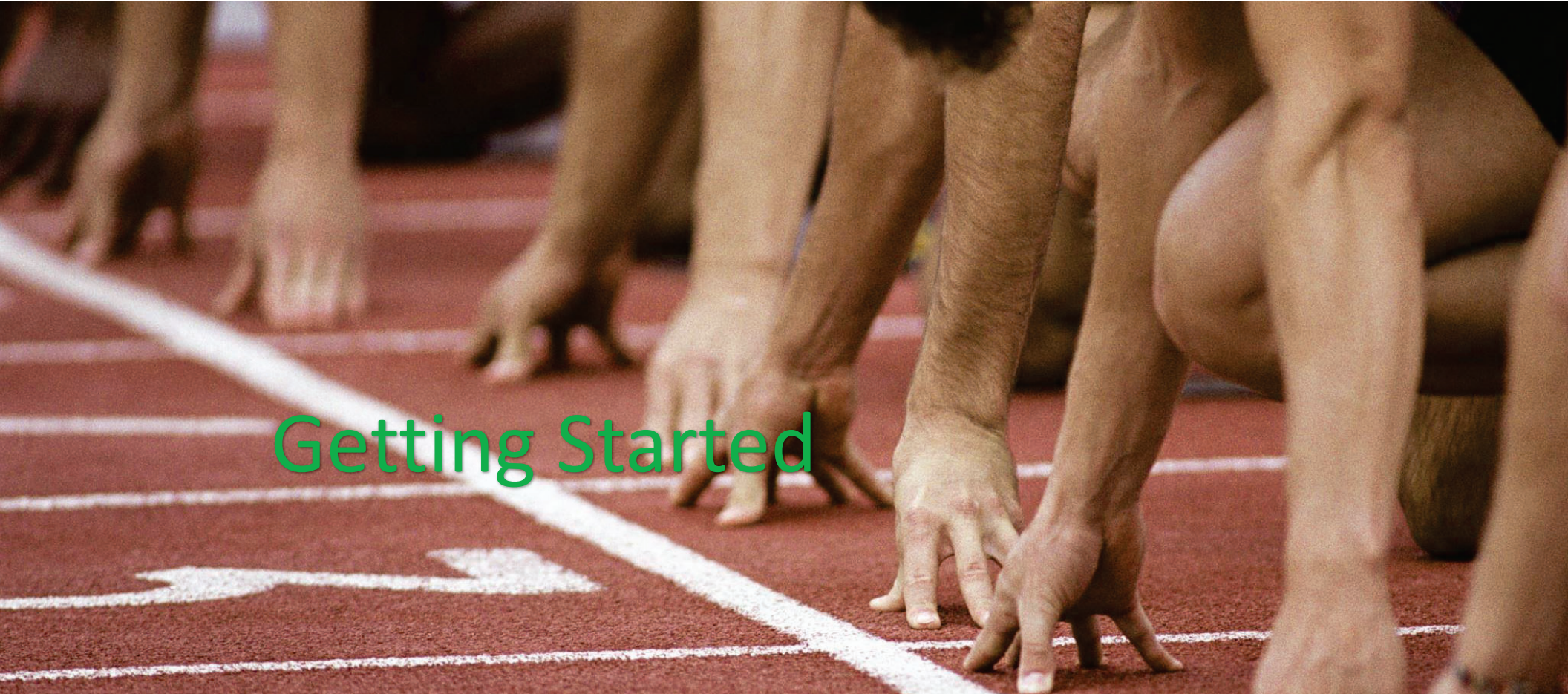Research partner of US Olympic & Paralympic Committee

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DEFINING A RESEARCH INSTITUTE

Essentially much what is true for a start-up company applies
here: starting with a small team, a strong mission, and the
motivation to develop ideas and bring them to fruition.
Creative concepts are of course key ingredients. Strong
leadership is important, yet true leadership means
absorbing and discussing ideas and input from all colleagues.
In some cases, leadership has to resist external forces that
try to push their favorite ideas or candidates.
….*Wolf B. Frommer*

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Getting Started

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IT ALL STARTS WITH AN IDEA

But that's just the start...

BUSINESS PLAN

Executive Summary
Company Description
Product/Science
Market Analysis/Freedom to Operate
Strategy & Implementation
Management Team
Financial Plan & Projections
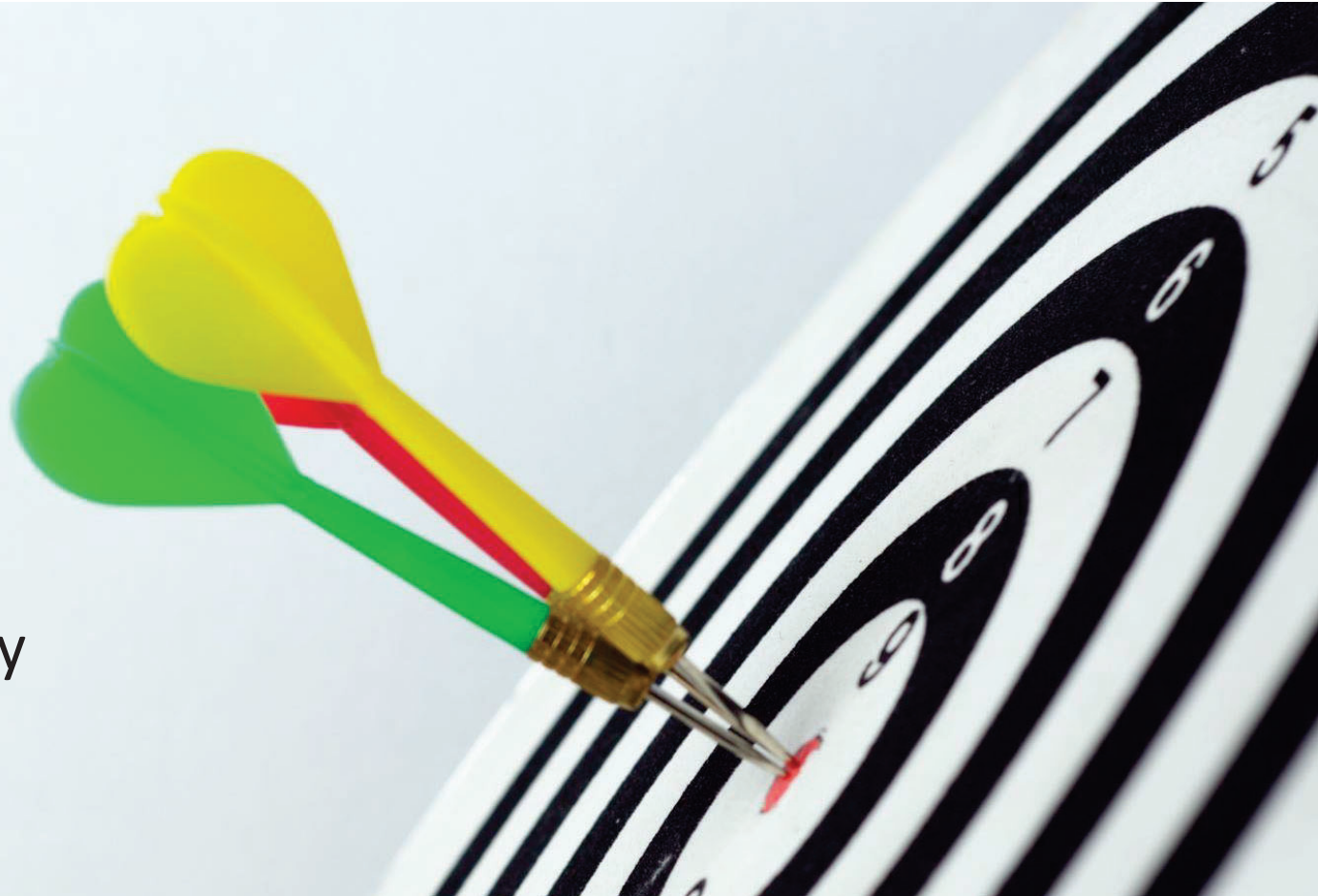➢ Get help from experts

FUNDING

Investors: Start a company? Non-Profit?
Strategic Partners
Grants
Philanthropy

DEFINE SUCCESS

- ❖ Financial
- ❖ Buy-out/IPO "exit"
- ❖ Rankings
- ❖ Publications
- ❖ Intellectual Property
- ❖ Grants

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Leadership Team: Critical for Success

Get the right mix
Scrutinized by investors
Not all visionaries make great leaders

Board of Directors: Outside, independent experts with prior board service

Scientific Advisory Board:

Subject matter experts
Strategic planning
Scientific direction
Have time to dedicate to your organization

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Leadership

Sets Overall Vision and Advocates for it

Develops Goals

Defines Metrics

Fosters Continuous Improvement

Makes sure goals, metrics, timelines and budgets are met

Promotes atmosphere

✓ intellectual curiosity, creativity

✓ teamwork

✓ trust, respect

✓ integrity

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Create Organizational Chart

Eliminate Silos

Common Goal

Stronger Together

Create Networks with other organizations

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SCIENCE TEAM

Scientists
Laboratory Staff
Technicians
Grant/Scientific Writers
Regulatory Experts

- ✓ Reward creativity
- ✓ Mentor junior scientists
- ✓ Strategize as a team on projects

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Administrative Team

✓ Important Team
✓ Allows scientists to focus
on **science**
✓ Don't skimp on quality as they
wear many hats

Finance/Legal/HR/IT
Grant Managers

➢ Consider outsourcing
certain functions
➢ Consider "leasing" staff

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Pre-Award	Post Award	Compliance/Integrity	Innovation
Feasibility Analysis	Award Set-Up	IRB	Identify IP
Identify funding opportunities	Award Management	FDA	Patents
Proposal development	Invoicing & Expense Tracking	Good Clinical Practice	Licenses
Research contracts	Reporting	Good Laboratory Practice	
Subawards	Award Closeout	Conflict of Interest	*signed policy,
Budgeting	Subrecipient Monitoring	Research Misconduct	motivate
Award Acceptance	F&A Rate Agreement	Billing Compliance	inventors
Reporting		Clinicaltrials.gov	
		Accreditations	
		Audits	
		Export Control	

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TEAM SUCCESS

- ✓ Common Goals
- ✓ Shared Vision
- ✓ Trust
- ✓ Leave Egos at the Door
- ✓ Spirit
- ✓ Compatibility
- ✓ Motivated to succeed: financial, new discoveries, publications?

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U.S. PARALYMPICS

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FACILITIES

Location
- ✓ Where people want to be
- ✓ Near strategic partners whose facilities and equipment you can use

Strategic Partnerships

Joint Appointments

Shared workspaces

Lease vs. Build

Lease vs. Buy Equipment

Manufacturing

➢ Invest in facilities to do it yourself
➢ Outsource to a 3rd party
➢ Pros & Cons

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Other Considerations

Corporate Filings
Trademarks & Maintenance
Patent Filings & Maintenance
Domain Registration
Tax Filings
Payroll
Timekeeping
Insurance:
➢ Health, Liability, Product/Clinical Trials,
  Auto, Business Interruption, Cybersecurity,
  Key Man
Regulatory Filings
Annual Reports

CONSIDERATIONS FOR GOVERNMENT FUNDING

- ✓ System for Award Management
  - Renewed annually
  - Can take several weeks to set up
- ✓ Dun & Bradstreet (DUNS)
- ✓ Cage Code
- ✓ Employee Identification Number
- ✓ Small Business Registration
- ✓ ERA Commons Registration
- ✓ Grants.gov Registration
- ✓ Financial Conflict of Interest Policy
- ✓ Institutional Review Board
- ✓ Institutional Animal Care & Use Committee
- ✓ Institutional Biosafety Committee

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MAINTAINING SUCCESS

Track metrics
Monitor your burn rate
Reports: Monthly, Quarterly, Annually
Don't be afraid to make changes anywhere, anytime
Research and Development Meetings
Governance: Board/Advisory Meetings

Innovate
Keep the team motivated
No silos
Shared Vision
Value the team
Celebrate successes

It Only Works...If Everyone Rows in the Same Direction

Thank you!