



JSS Recherche médicale
Medical Research



The Canadian Experience: Requirements for a Successful Health Care Research Organization

A **science-based** clinical
research organization
that bridges **academics**
& **industry**

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www.jssresearch.com

JSS Medical Research



Canadian-based full service
Contract Research Organization
(CRO)

Office in Bogotá, Colombia

+25 years in business

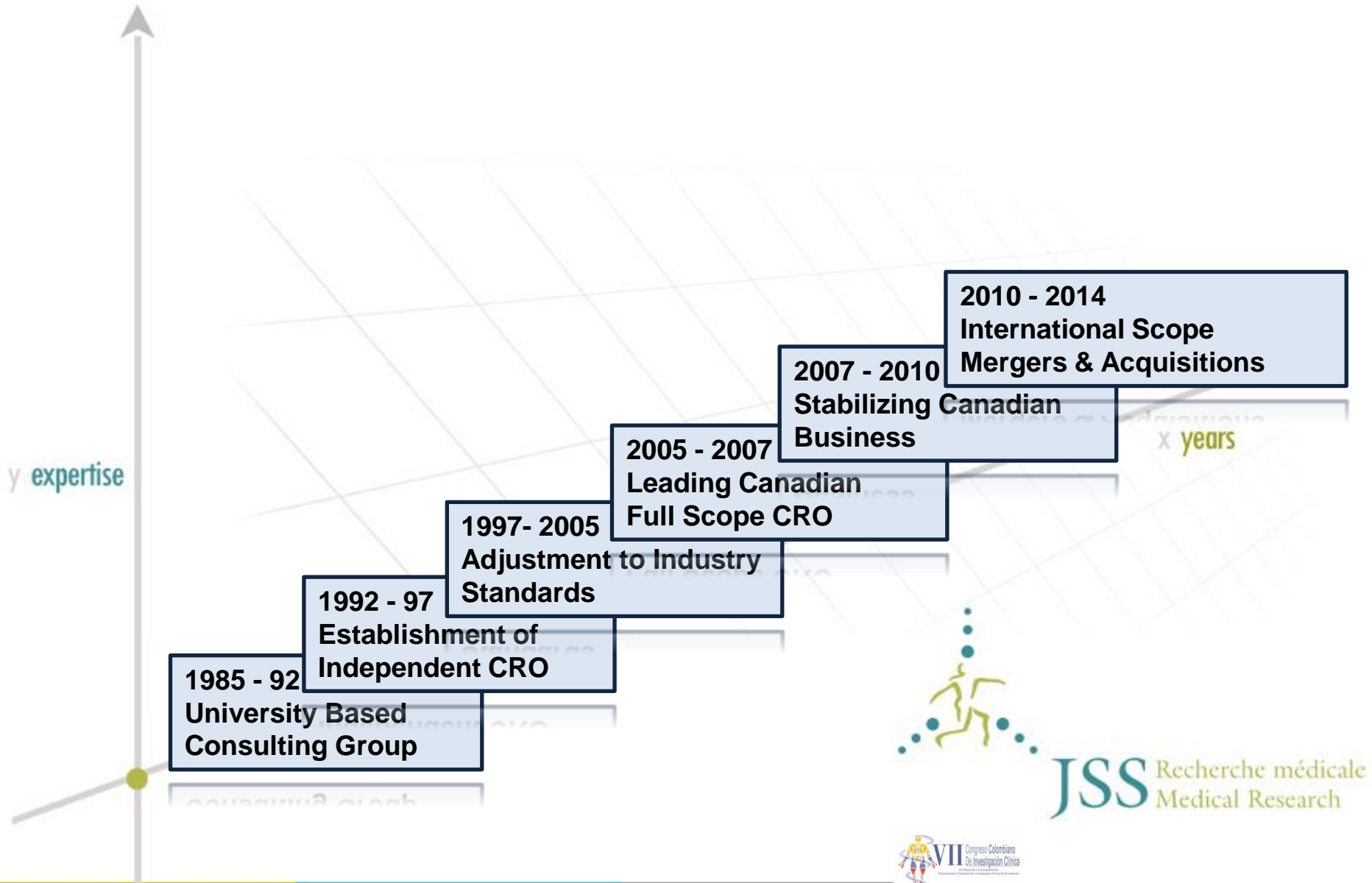
Privately held and financially
stable

Experienced management team

Sponsor centric (>70% repeat
business)

89 full time + 49 regionally
based contract staff

JSS Medical Research is a full service clinical research organization



Senior Management

John Sampalis PhD
President, CEO & Chief Scientific Officer

Stella Boukas BA, CCRP
Chief Operations Officer

Joanne Watson MSc
Chief Business Development Officer

Emmanouil Rampakakis PhD
Vice President Scientific Director

Francois Le Barbenchon BSc
Director of Clinical Operations

Sanjay Machado MD
Executive Director, Global Business Operations

Norman Elliott MSc
Executive Director, Business Development

Marta Lia Valencia MSc
Business Officer South America

Marianna Boukas BA
Executive Director, Quality Assurance

Michel Bordeleau BSc, MBA
Global Director of IT

Nadia Longo MSc
Director, Business Operations

Toni Rinow MBA PhD
Chief Financial Officer

Julie Vaillancourt BSc, MSc, PhD Candidate
Senior Director of Academic Research

Yohana Granados MSc
Director of Clinical Operations Latin America

Marie Maxime Hubert MSc
Manager Market Access & HEOR

Fridon Chouha MD (M.B.Ch.B.)
Director, Medical Liaison

* Part time consultant



A science-based organization with wide and deep academic affiliations and ability to work with associations

Academic Affiliations

Dr. John Sampalis, President

BSc, BA (Hon.), MSc, PhD, F.A.C.E.

*Associate professor (tenured),
department of surgery (McGill
University and University of Montreal)*

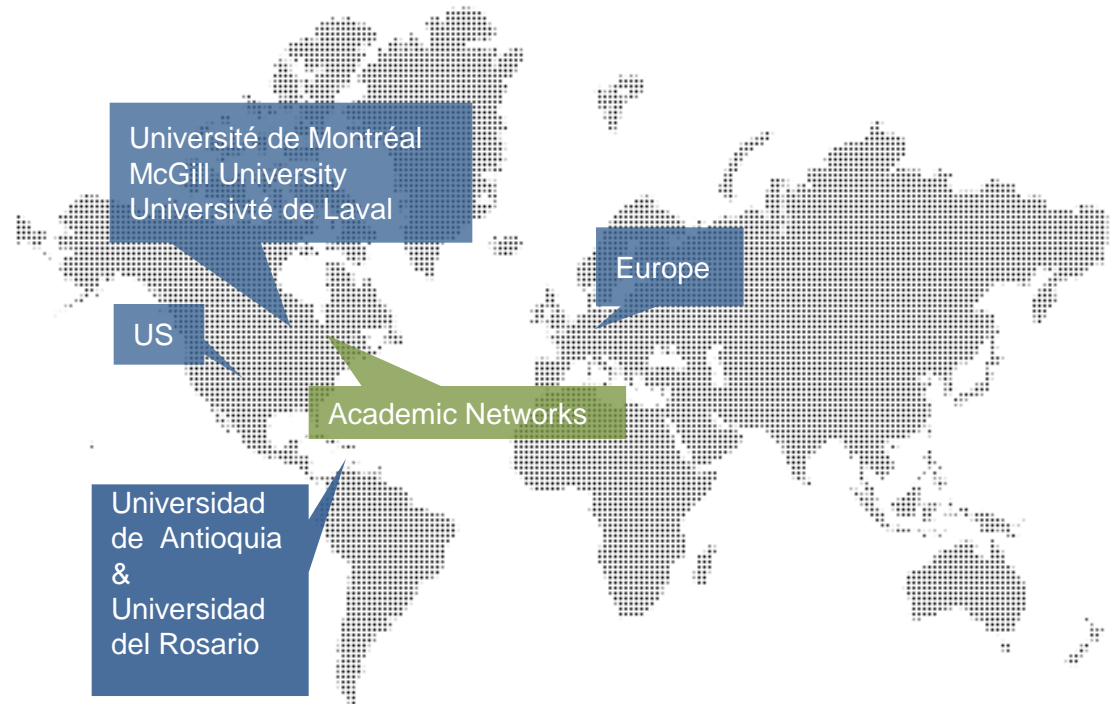
*Director of surgical research (Jewish
General Hospital)*

*Head of the surgical epidemiology
division (McGill University)*

Senior Management: *Members of
faculty at internationally recognized
universities*

**Ongoing relationships with Medical
Schools** in Canada, US, Europe and
South American Universities

Access to Academics and KOLs in
Canada, US, Europe and South
American Universities



Other affiliations

- American Association for the Surgery of Trauma
- Canadian Arthritis Network
- Canadian Obesity Network
- Canadian Rheumatology Research Consortium
- Canadian Urology Research Consortium
- Quebec Ministry of Health
- Ontario Ministry of Health
- Ontario Best Practices Research Initiative

Our global reach allows us to provide services in all developmental phases

Offices

Montreal, Canada & Colombia with clinical research staff located in Costa Rica, Guatemala, Peru, Panama, Venezuela and Ecuador and access to Mexico, Argentina, Brazil and Chile with partners

Partners

Environics (Canada)
Venn-Life Science (Europe)
NEOX (Europe)
ICOM (Egypt)
CCBR (Brazil)
Salutis International (Spain)
Max Neeman (India)



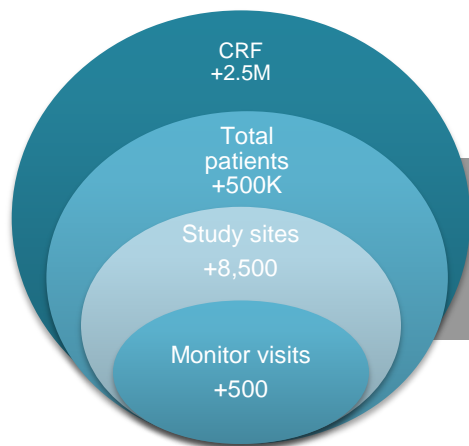
Offices



Countries where JSS Medical Research is active

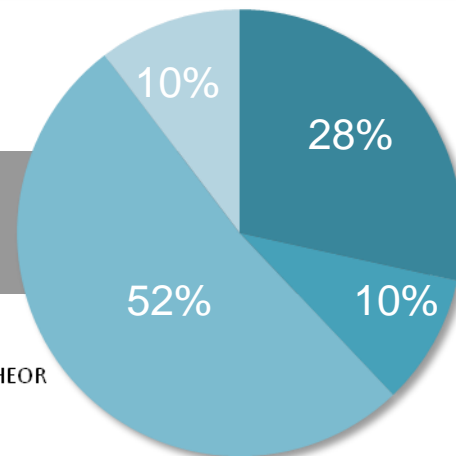
Proven expertise in Research across all Phases

+350 projects in the last 5 years



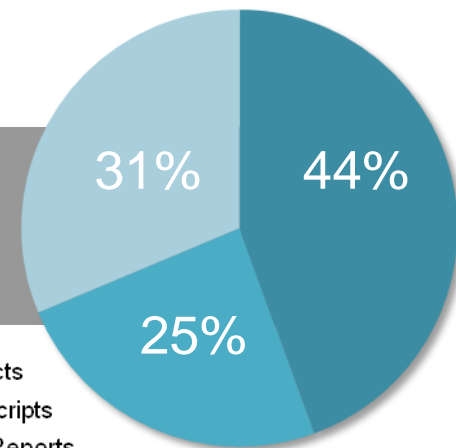
Over 500,000 patients processed
At +8,500 sites in the last 5 years

- II/III
- IIIb/IV
- PMOS/HEOR
- IIS

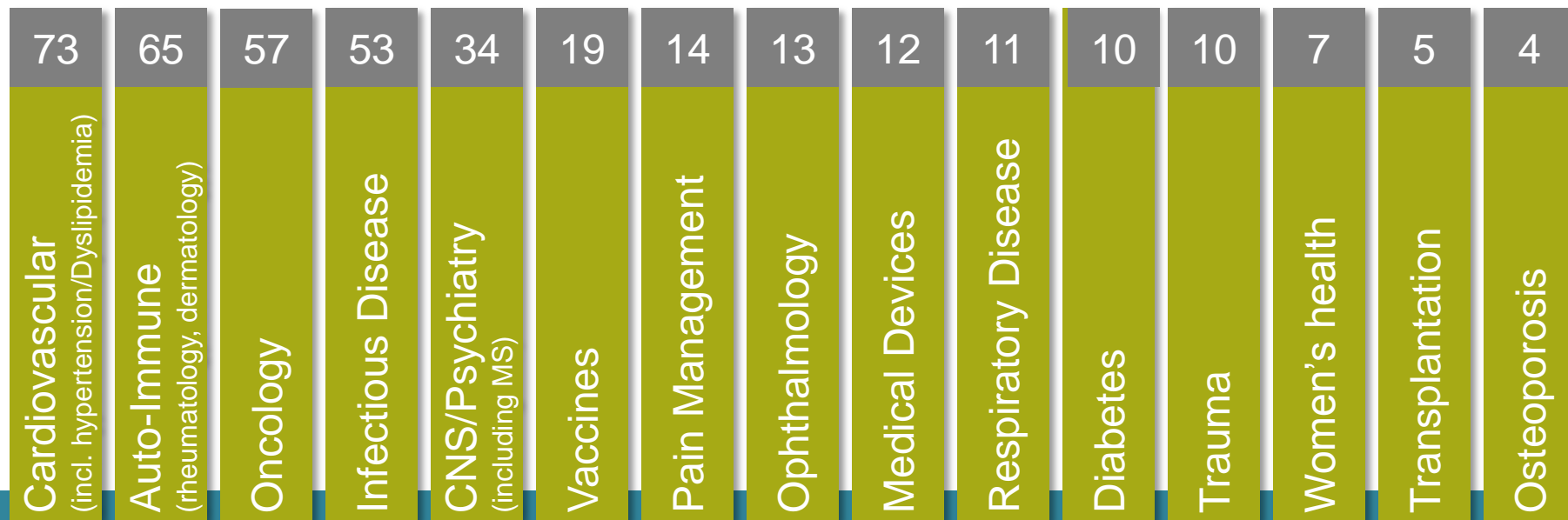


>200 publications in the last 5 years

- Abstracts
- Manuscripts
- Study Reports



Sponsors can rely on our expertise in a wide range of therapeutic areas



Number of Projects by Therapeutic Areas (past 5 years)

We offer solutions & insights for sponsors' developmental phases & post-approval needs

Drug development

Clinical Phase I-III

- Phase I
- Phase II
- Phase III-IIIb

Late and post-approval phase

- Phase IV
- PMOS
- Chart Review
- Registries
- Databases Analysis

Market Access & HEOR

- Health Technology Assessment
- Value Proposition
- Budget Impact Analysis
- Health Economic Studies
- Patient Journey

Across the lifecycle

- Program Development
- Needs Assessments
- Strategic Assessments
- Risk Management
- Epidemiological Studies
- Literature Review
- Meta Analysis
- Best Evidence Synthesis
- Advanced Biostatistics
- Rescue Analysis

JSS Medical Research Capabilities

Requirements for a Successful Health Care Research Organization

1. Subject Matter:

- *The subject matter of Health Care Research is **SCIENCE***
 - The essential ingredients of any *health research program* are derived from one or more of the following disciplines:
 - *Physiology*
 - *Biology*
 - *Biochemistry*
 - *Medicine*
 - *Psychology*
 - *Sociology*
 - *Epidemiology*
 - *Biostatistics*
 - *Health Economics*

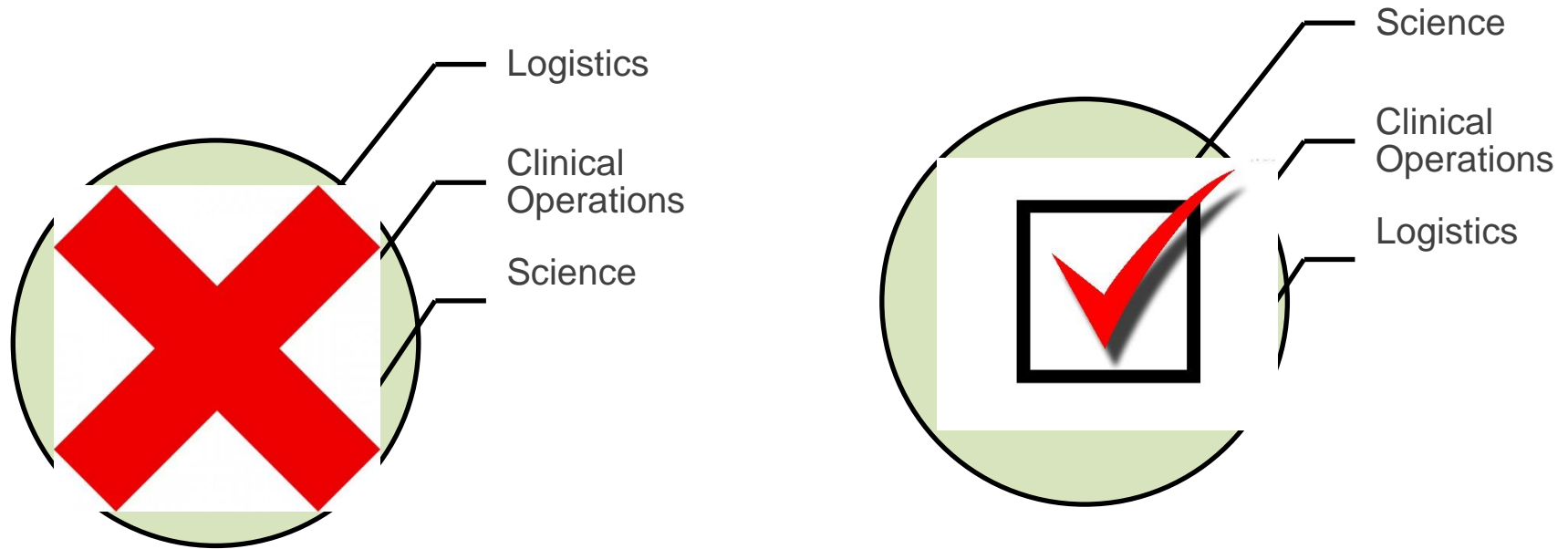
Any organization / entity involved in health research must have a strong foundation in one or more of the above sciences and be capable of accessing the others as needed to create a multidisciplinary scientific team.

2. Academic Links:

- Strong Scientific Foundation:
 - Is essential
- Academic Institutions with Medical Schools and Research:
 - Incubators of Scientific Excellence and Advancement
 - Key Opinion Leaders
 - Researchers
 - Teachers
 - Medical Students
 - Graduate Students in Life Sciences
 - Residents
 - Post Doctoral Fellows

Any organization / entity involved in health research must have affiliations or at the minimum strong relationships / alliances with academic institutions.

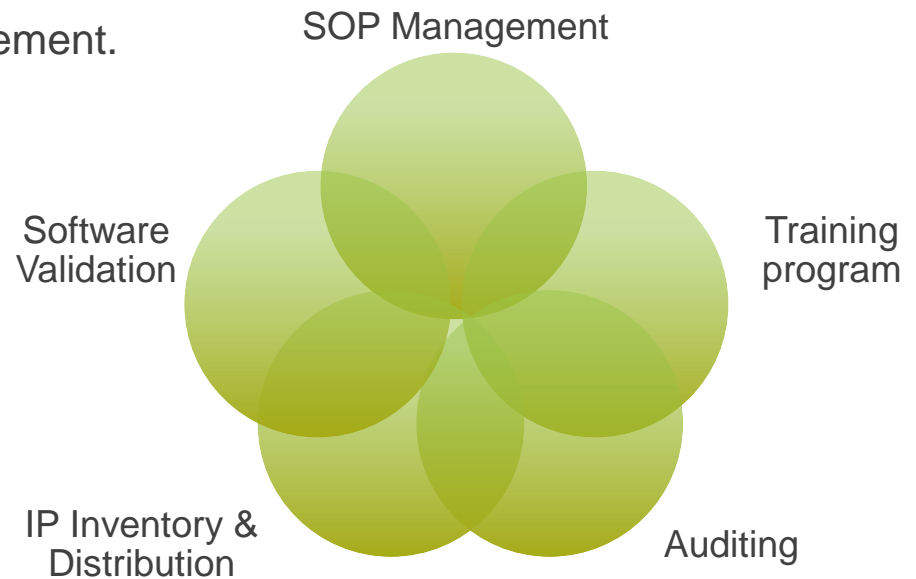
3. Science as the Foundation for Logistics & Operations:



Establish science as the core and then build clinical operations and logistics on the basis of scientific excellence; not the other way around

4. Quality Assurance:

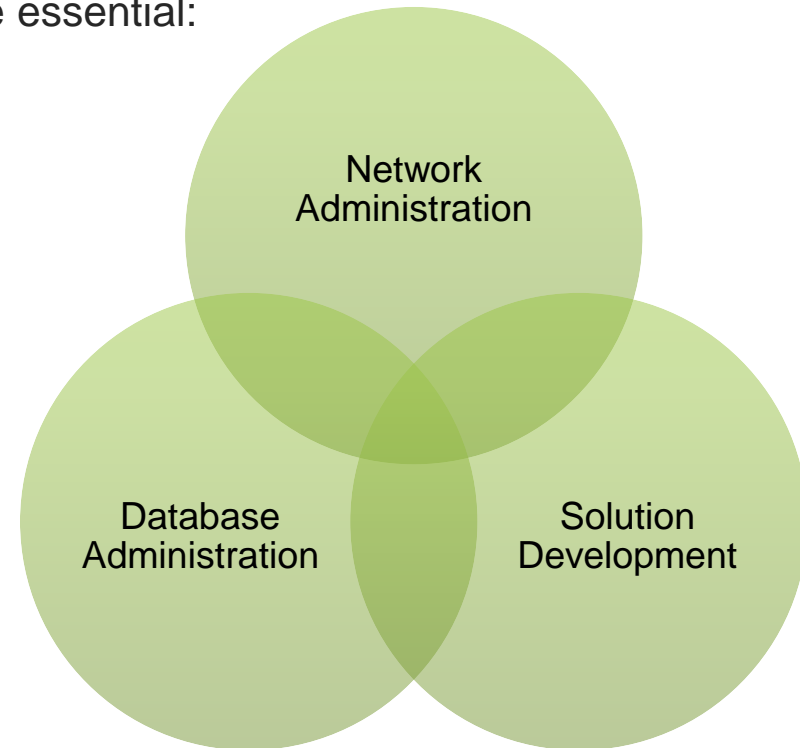
- Establish Strong Quality Assurance Program:
 - Independent from Operations and Science.
 - Reporting to CEO or Upper Management.
 - No – Compromise to Standards
 - Highest non-tangible investment



Any organization / entity involved in health research must ensure the credibility of the researchers / investigators and the reliability and validity of the results: ZERO tolerance

5. Information Technology:

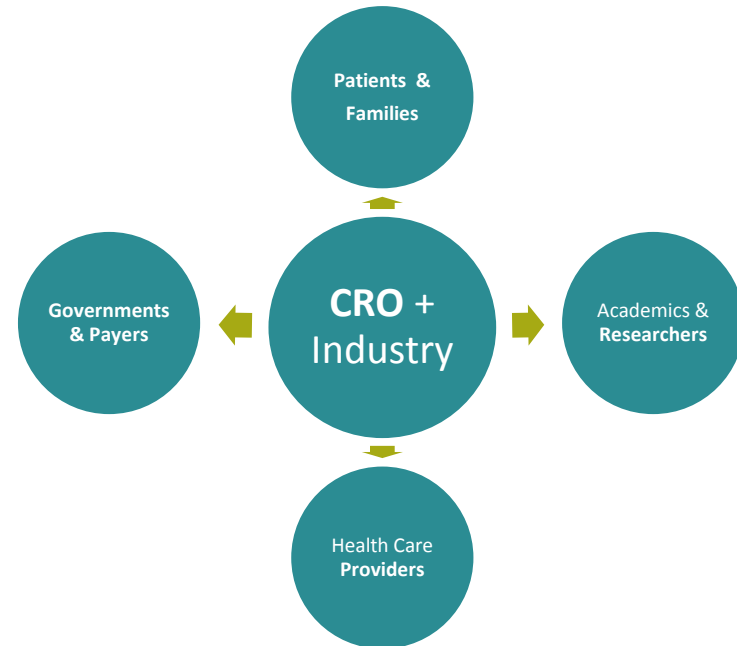
- High Quality and Reliable Computer Systems are essential:
 - Electronic Data Capture
 - Study Progress
 - Remote Monitoring
- Reliable and Validated Systems
 - Regulatory Compliance
 - User Friendly
 - Intuitive
- Communication:
 - Internal and External
- Information (Knowledge) Management:
 - Transparency
 - Continuity
 - Disaster Recovery
 - Risk Minimization



Information Technology must be a FACILITATOR: NOT A DRIVER of Processes.

6. Value Proposition:

- Health Care Research Organization MUST:
 - Address the NEEDS and Provide Value to all Stakeholders
 - Neglecting any one of them:
 - Unacceptable
 - Ultimately lead to failure



Any organization involved in Health Care Research CANNOT operate in isolation and MUST address the needs of ALL Stakeholders without compromise

7. Finance:

- Fiscal Control is Essential
 - Profitability to Ensure Viability of the Organization
 - Pricing of Services:
 - Competitive
 - Reasonable Profit Margins
 - Expenses:
 - Monitored and Controlled
 - Without Compromise of Quality
 - Cash Flow Management:
 - Survival of the Organization
 - Balance of Accounts Receivable and Payable

Financial management is ESSENTIAL: Otherwise the organization will either fail (everyone loses) OR the quality will be compromised (everyone loses).

8. Adaptation:

- Health Care:
 - Dynamic with Constant Changes Driven by:
 - Treatment Gap
 - Safety Gap
 - Knowledge Gap
 - Must adapt to the contemporary needs:
 - Drug Development Phase
 - Therapeutic Areas
 - Demands:
 - Discovery (New Treatments)
 - Needs Assessments (Gaps)
 - Health Economics
 - Comparative Effectiveness

Health Care Research Organizations must conform to the changes in the critical issues and priorities.

9. Support:

- Health Care Research MUST BE Facilitated:
 - Governments:
 - Financial:
 - Tax Credits to Industry
 - Development:
 - University and Researcher Support
 - Expansion:
 - Community Physician Involvement
 - Regulatory Agencies:
 - Enable NOT Disable
 - Strict BUT Reliable
 - Decisive BUT Efficient

Governments and Regulators must first Protect the Patients and Population BUT must also create environment of cooperation to allow research to be realized.

Thank You!

JSS Medical Research Inc.

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