

# Rescue Trials Succeed When ...

Scimega Research  
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# Clinical Trial Road blocks

Despite methodical planning, clinical trials can hit unexpected roadblocks:

- Resource shortages
- Unforeseen service needs
- Contractual issues
- Activation Delays
- Recruitment problems, poor participants retention





# Rescue Study Insights for Success

- Spot the Red Flags Early
- Right Timing & Cost Analysis
- Case Studies Highlight Key Factors for Success
- Measuring Rescue Strategy Target Attainment



# Why Biotechs Need Reliable Rescue Solutions

- ✓ Oncology development timelines are aggressive
- ✓ Setbacks threaten investor confidence and milestones
- ✓ Canada offers rapid re-activation capabilities for rescue trials



**Enrollment at US sites  
going well - except in a  
targeted cohorts  
(TNBC)**

**Challenge due to  
competing trials and  
limited population**



## **The Context**

Phase 1/2 trial, Solid Tumors



## **The Solution**

Opened 3 Canadian sites with capacities in these cohorts; no/low competing trials.



## **The Results**

**Enrollment picked up on targeted cohort:**  
Sponsor met data analysis milestones and plans for dose expansion



# Canada: A High-Performance Research Environment

## Fast ethics & regulatory processes enable rapid rescue

- Health Canada = default 30-day review & efficient amendment pathway
- Multi-site ethics approvals accelerate activation

## Large Oncology Patience Pools across major tumor types

- 14% trial participation rate

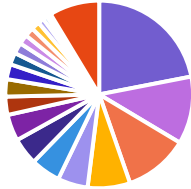
## High PI engagement improves enrollment consistency

- Referral-based system routes eligible patients to trial centers



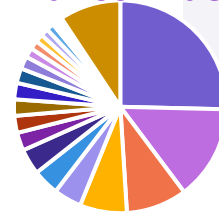
# 'TOP' Cancer Types in Canada

Number of Cancer Cases  
Males



- Prostate
- Lung and Bronchus
- Colorectal
- Bladder
- Non-Hodgkin lymphoma
- Melanoma
- Kidney and renal pelvis
- Head and Neck
- Leukemia
- Pancreas
- Liver and intrahepatic bile duct
- Stomach
- Multiple myeloma
- Esophagus
- Thyroid
- Brain/CNS

Number of Cancer Cases  
Females



- Breast
- Lung and Bronchus
- Colorectal
- Uterus (body, NOS)
- Non-Hodgkin lymphoma
- Melanoma
- Thyroid
- Pancreas
- Kidney and renal pelvis
- Ovary
- Bladder
- Leukemia
- Head and Neck
- Multiple myeloma
- Cervix
- Liver and intrahepatic bile duct
- Brain/CNS
- Stomach
- Soft tissue (including heart)
- Esophagus
- Hodgkin lymphoma
- All other cancers

**Heavily Screened Nationally: Prostate, CRC, Breast, Ovarian, Lung Cancer - % varies geographically**

# +50 Active Cancer Centers in Our Network

We have privileged & professional relationships with over 50 cancer research centers.

Our **Canadian investigators stand as formidable global figures in medical research**, renown for their expertise, innovation, and collaborative spirit.

The healthcare culture in Canada **favors referrals among oncologists and centers**, thus eligible patients are sent to sites with such capacities.



**Scimega**

EXPERTS IN CLINICAL ONCOLOGY

[www.Scimega.com](http://www.Scimega.com)



# Reasons Canada Appeals to Oncology Biotechs

- **Lower operational and monitoring costs** vs. U.S. and other regions
- **Canadian sites outperform** global averages in trial enrollment
- **High protocol adherence** enhances reliability
- **Low participant drop out** of treatment (often zero)
- **World-class KOLs** drive strong scientific credibility
- **Highly diverse** Canadian population
- **Inspection-ready data** from experienced oncology sites
- **More predictable delivery** of trial milestones



**Dose-escalation at 2 European countries**

**6 weeks into Canadian feasibility via global partner yet zero response**

**Additional European countries activation delayed**



## **The Context**

Phase 1/2 trial, Solid Tumors then gyne focus in expansion



## **The Solution**

Identified 3 first sites in the 1<sup>st</sup> week with QVs within 3 weeks.

Ethics subm within 1 month, activation of 1+2 sites within 3.5 months, followed by +3 sites within next 2 months.



## **The Results**

**6 Canadian activated within 6 months.**

**1<sup>st</sup> study volunteer screened within 2 weeks of 1<sup>st</sup> site activation.**

**100% sites are enrolling.**

Real-Life Case Study of  
Trial Conducted in Canada

[www.Scimega.com](http://www.Scimega.com)



**Phase 1 RLT opened at 2  
Australian sites; 2  
additional sites planned  
for activation**

**Sponsor wants to avoid  
enrollment delays**



## **The Context**

Phase 1 trial, CRPC,  
Radioligand trial (imaging + tx);  
high screening failure rate  
expected



## **The Solution**

Identified 2 Canadian sites  
during feasibility & proposal.  
Start-up planned within 3  
months. Both sites activated  
under same ethics approval;  
1 site preps RL onsite, other  
site uses external  
radiopharmacy.



## **The Results**

**Canadian sites started  
contributing within 4<sup>th</sup> month of  
our involvement.**



# Niche Canadian Oncology CRO

WITH EXPERTISE IN SMO ACTIVITIES FOR CLINICAL ONCOLOGY

Singular focus on the successful conduct of cutting-edge ONCOLOGY clinical trials in CANADA

YEARS  
**29**

## EXTENSIVE TEAM EXPERIENCE

- Phase 1, 2 & 3 onco/heme trials
- Traditional, Umbrella & Basket
- Registrational trials
- Inspections
- Late-stage disease
- Rare cancer types
- Immuno-oncology
- Radionuclides

Proven track record of successful study conduct in Canada

Bundled with 3 decades of lessons learned!

Extensive network of +50 cancer research centers across Canada

Skilled & Experienced in Optimal vendor teaming

[www.Scimega.com](http://www.Scimega.com)



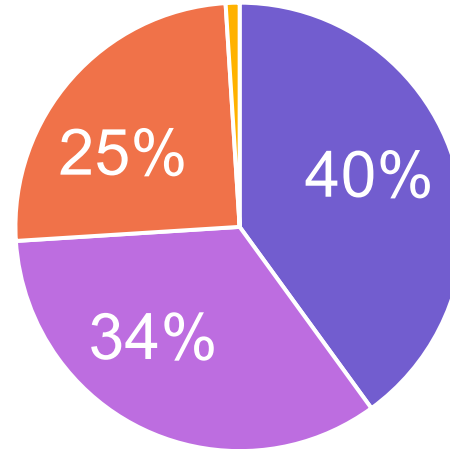
# Access Canada with Scimega for Strategic Advantage

**Deep oncology expertise** supporting complex trials

**High-performance team** for rescue strategies

**Accelerate timelines** and stabilizes global programs.

29 Years of Onco/Heme  
Trial Experience



■ Phase 1 ■ Phase 2 ■ Phase 3 ■ Phase 4

# What is our MEASURABLE Difference?

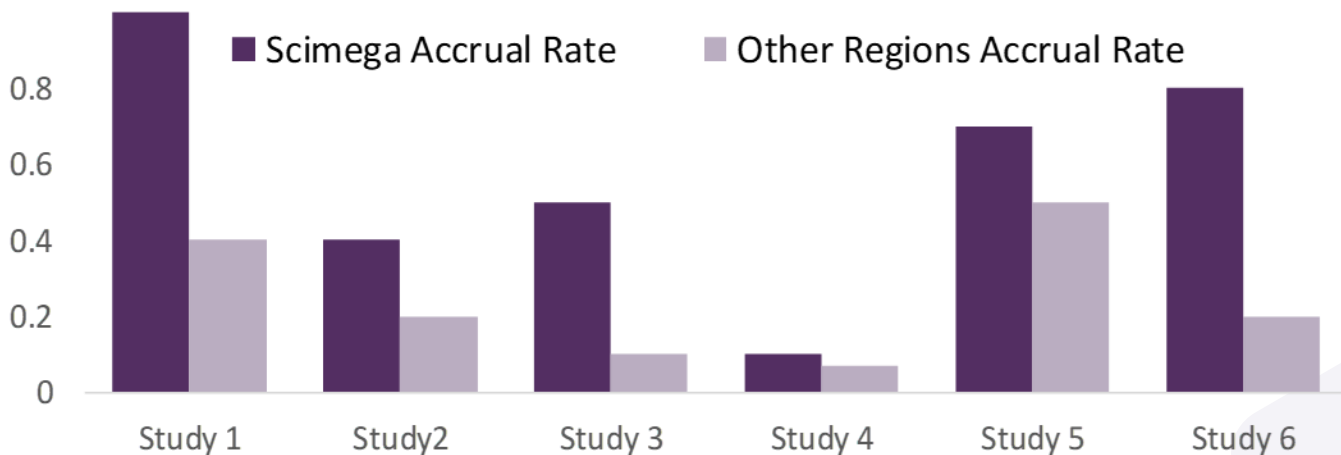
**29 Years working exclusively** with Canadian Cancer Research Centers

**You can't imitate that!**

**Strong and well-established relationships** with site teams

**Very low employee turnover** – Guarantees optimal continuity during a project

**Higher accrual rate to trials** compared to other CRO's in Canada.



# REAL-TIME FEASIBILITY ASSESSMENT DATA MATTERS MORE THAN EVER FOR

Faster decisions - More robust expansion planning -  
Better support of choices between regions

## REAL-TIME DATA FOR A REAL-WORLD PACE

Clinical trials move fast in today's complex research environment; real-time data doesn't just improve efficiency – it can improve the entire prospect for successful study outcomes when it matters most.

YEARS  
**29**

*This process should not be taking 4-6 months. The data you seek must be very fresh. Provided to you with no more than a one-month time stamp, and available to you within 2-weeks.*

Real-Time Feasibility  
in 2-wks Inquire Now

**Scimega**

EXPERTS IN CLINICAL ONCOLOGY

Interested in Exploring the  
Canadian Opportunity?



Visit Our Website

[SCIMEGA.COM](http://SCIMEGA.COM)



## eTMF

Completeness Across  
Active Trials **98%**

## Verified

Participant Source Docs  
Completed During Study  
Conduct **89%**

## Visit Reports

Submitted On Time  
to Sponsor **100%**

## SITE INVOICE COLLECTION RATE



**ZERO**  
Major Audit  
Findings

For all Scimega  
Operations

**ACCURATE SITE  
PAYMENTS ON  
TIME/CONTRACT**  
**100%**

**Study Participant  
Dropout Rate**  
**0%**

**Oncology CRA  
& PM Turnover**  
**<5%**

**Team Compliance on Scimega's  
Continuous Oncology Training  
Curriculum**



YEARS  
**29**