

# Canadian Clinical Trial Summit

Canada's Research-Based  
Pharmaceutical Companies



Les compagnies de recherche  
pharmaceutique du Canada



CIHR IRSC  
Canadian Institutes of  
Health Research    Instituts de recherche  
en santé du Canada



## Break-out Sessions

### *Cost Structure*

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# Agenda

- Why do trials matter?
- **Site level experience**
  - Cost drivers & concurrent financial pressures
  - Impact on trials infrastructure
- **Industry experience**
  - Pressure on industry from increasing R&D costs
  - Clinical trial costs
  - Generating value from clinical trial investment
- **Discussion**

# Why We Care About Diminished Trials Activity in Canada?

Patient care will be negatively impacted by reducing:

- Access to novel therapies
- Clinician exposure & uptake of new therapies
- Canadian data in regulatory dossiers (**coverage**)
- Knowledge translation/exchange related to clinical research
- Non-trial research is conducted using infrastructure (investigator-initiated studies, registries, etc.)

# Canada Within the Global Drug Development Environment – Impact of Value for Investment

- Development is driven globally & participation is influenced by recruitment and cost
- Site cost to set up one study = ~\$12-15,000
  - Inadequate budget & poor recruitment = no recovery of sunk costs = decreased site viability
- Industry cost to set up one trial site = ~\$22,000
- Poor recruitment = poor value for investment = sites don't participate in the future

# Cost Drivers at the Site - Rising Protocol Complexity, Burden and Impact (All TAs, All Phases)

| Change in Complexity                                | 2000 – 2003 | 2004-2007 | Percentage Change |
|---|-------------|-----------|-------------------|
| Unique procedures per protocol (median)             | 20.5        | 28.2      | 38%               |
| Total procedures per protocol (median)              | 105.9       | 158.1     | 49%               |
| Total investigative site work burden (median units) | 28.9        | 44.6      | 54%               |
| Total eligibility criteria                          | 31          | 49        | 58%               |

| Impact of Protocol Complexity                    | Less Complex | More Complex | Difference |
|--|--------------|--------------|------------|
| Case report form pages - #per protocol (median)  | 55           | 180          | +227%      |
| Time - Protocol Ready to last patient last visit | 413 weeks    | 714 weeks    | +72%       |
| #Amendments                                      | 1.9          | 3.2          | +68%       |
| Study volunteer enrollment rates                 | 75%          | 59%          | -21%       |
| Study volunteer retention rates                  | 69%          | 48%          | -30%       |

**Site remuneration: grant dollars per procedure per protocol paid to sites has **declined by 7% annually** when adjusted for inflation**

Source: Tufts CSDD

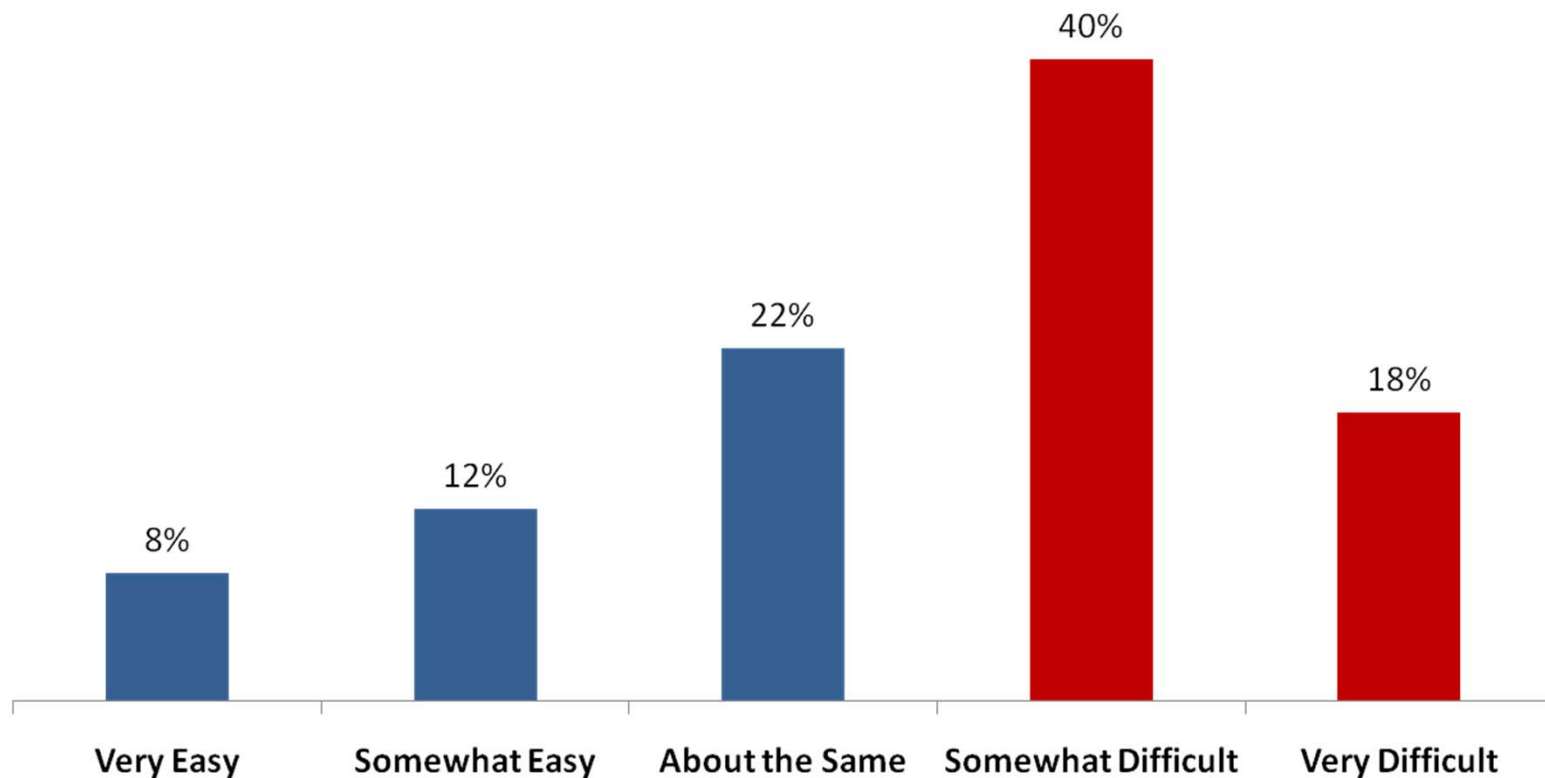
## Other Cost Drivers at the Site Level

- Outsourcing to CROs
  - Chaotic & fragmented management
  - Complicated contract negotiations
- Delays in start-up
- Increased regulatory compliance burden
- Challenges with recruitment - trials not viable economically

# Corresponding Financial Challenges

- Start-up activities are not cost recovered
- \$\$ paid per procedure declining annually
- Increase in unpaid activities
- Payment delays cause major cash flow challenges
  - ~120 days to payment; expenses paid in 45 days
  - hold back payments despite completed work
- Poor recruitment means limited cost recovery
  - 20% of sites fail to enroll a single patient; 30% under-enroll  
(Source: CIS)

# Compared to Three Years Ago, How Easy or Difficult is it for Your Site to be Profitable?



Source: Tufts CSDD – ACT Global Site Landscape Survey, N=2,721; 2010

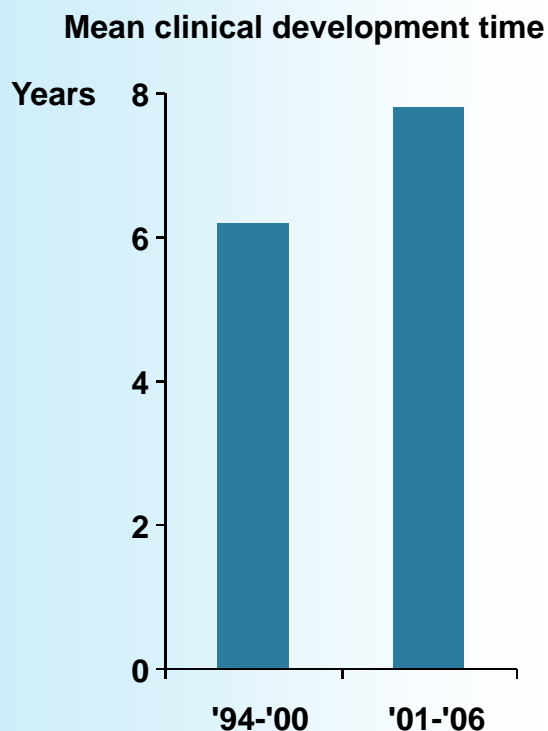


# Impact on Trials Infrastructure in Canada

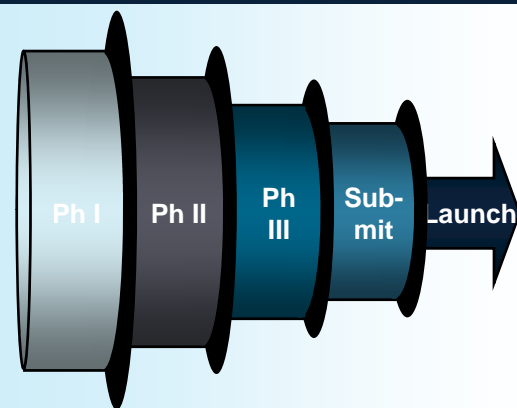
- Trial sites are losing money
  - Using other sources of income to offset trial losses
    - revenue from patient care, SR&ED, infusion clinic, other grants
  - Downsizing staff or no longer conducting trials
- Fewer young clinicians willing to conduct trials
  - Too risky financially & not enough infrastructure support
  - Considerable amount of work with a high probability of failure

# Growing pressure on clinical trial industry from rapidly increasing R&D costs

## Clinical timelines increasing



## Success rates deteriorating



1994-1997

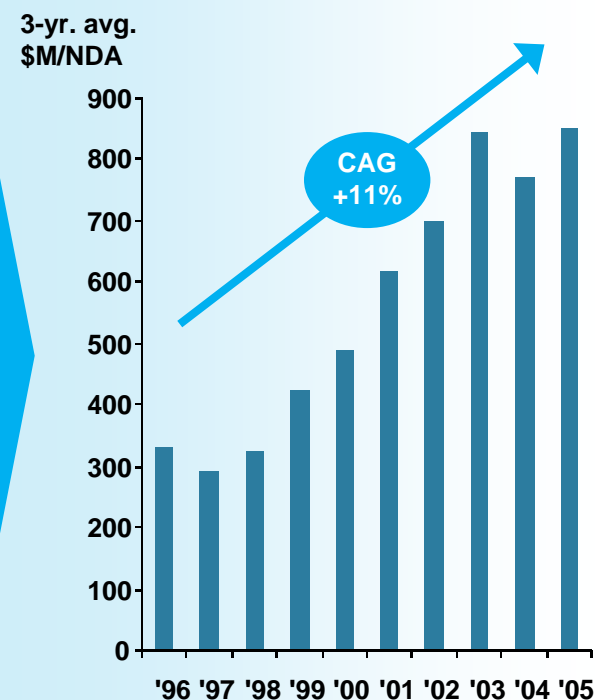
|     |     |     |     |     |     |
|-----|-----|-----|-----|-----|-----|
| 5.6 | 3.8 | 1.8 | 1.2 | 1.0 | 18% |
|-----|-----|-----|-----|-----|-----|

1998-2000<sup>1</sup>

|      |     |     |     |     |    |
|------|-----|-----|-----|-----|----|
| 11.7 | 6.9 | 1.9 | 1.1 | 1.0 | 9% |
|------|-----|-----|-----|-----|----|

Cumulative success rate

## Driving rising R&D costs<sup>2</sup>



1. Measured in 2004, however includes drugs that had a full status as of 2000

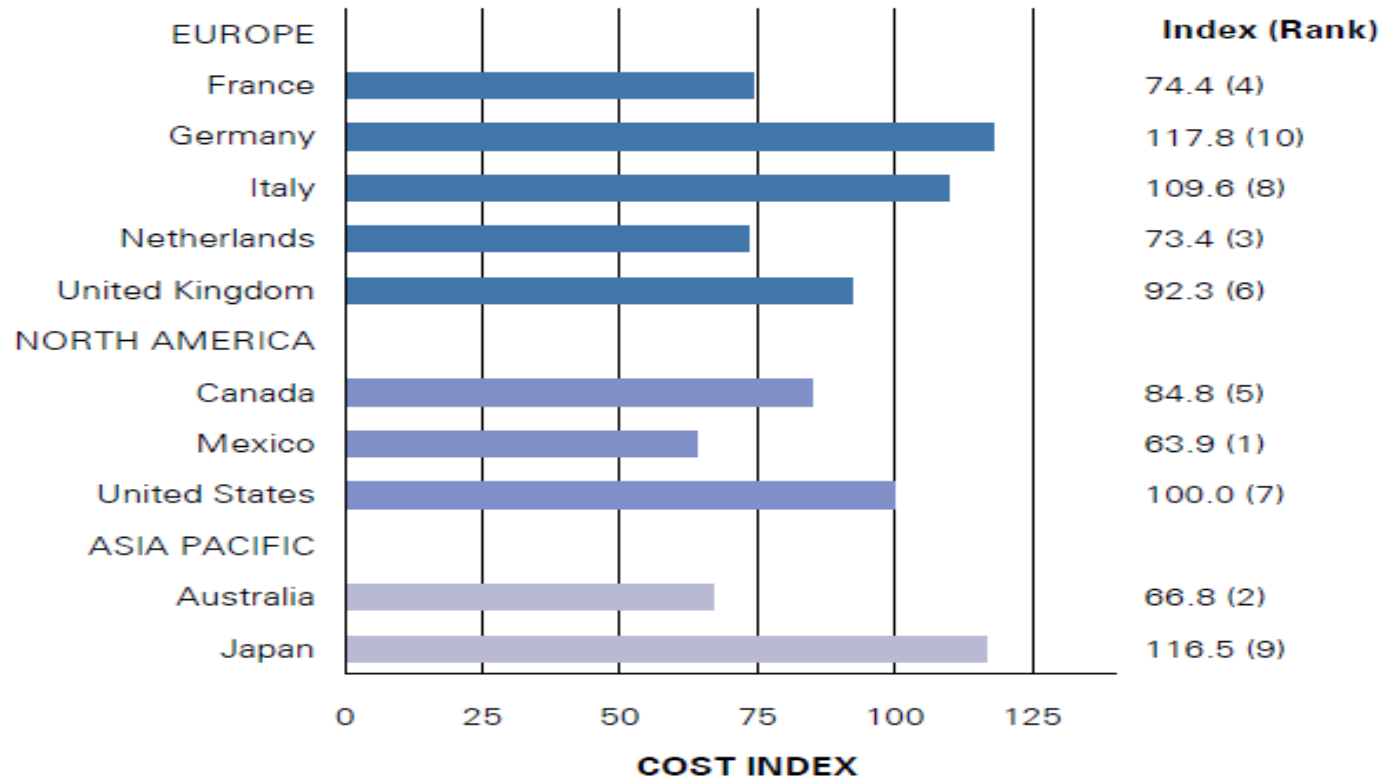
2. Amortized R&D expense vs. NDA output (rolling three-year average, 1996-2005)

Source: FDA Web site, PhRMA "Pharmaceutical Industry Profile 2006", Pharmaprojects, Tufts CSDD, Parexel, CMR, BCG analysis

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# Clinical Trial Costs

## Clinical Trials Management – International Results (US = 100.0)



Competitive Alternatives: KPMG's Guide to International Business Location 2010 Edition

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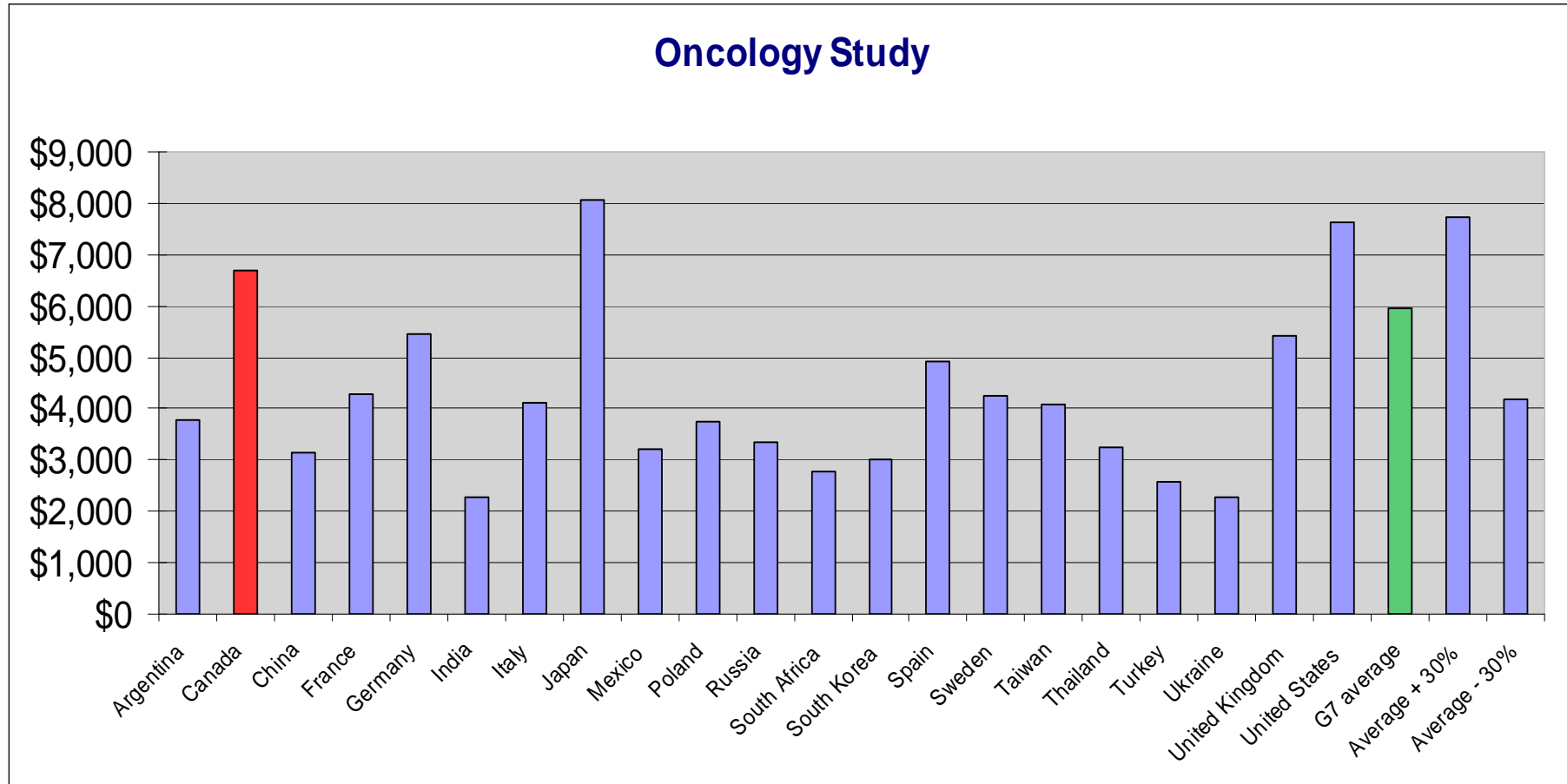
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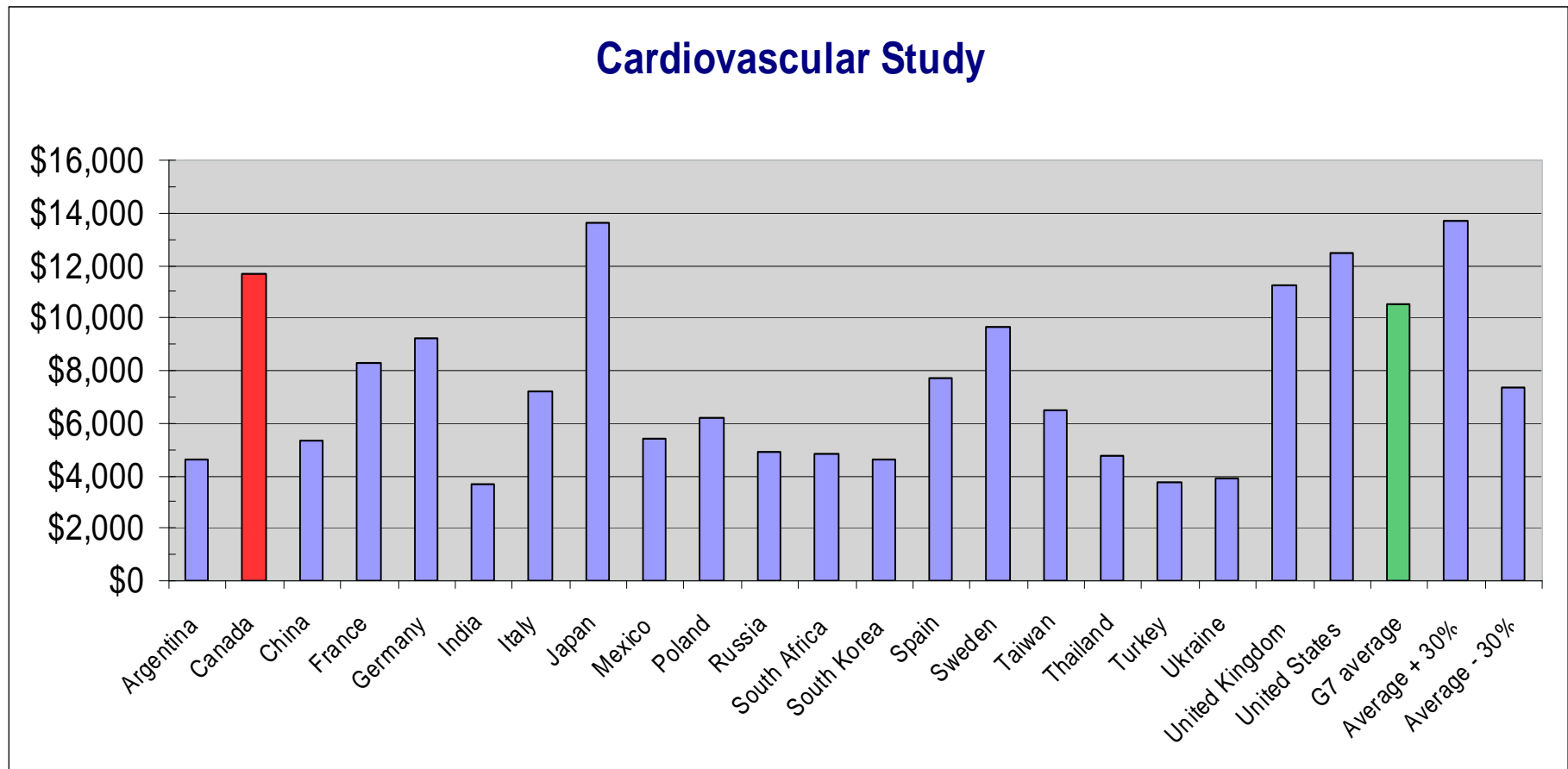


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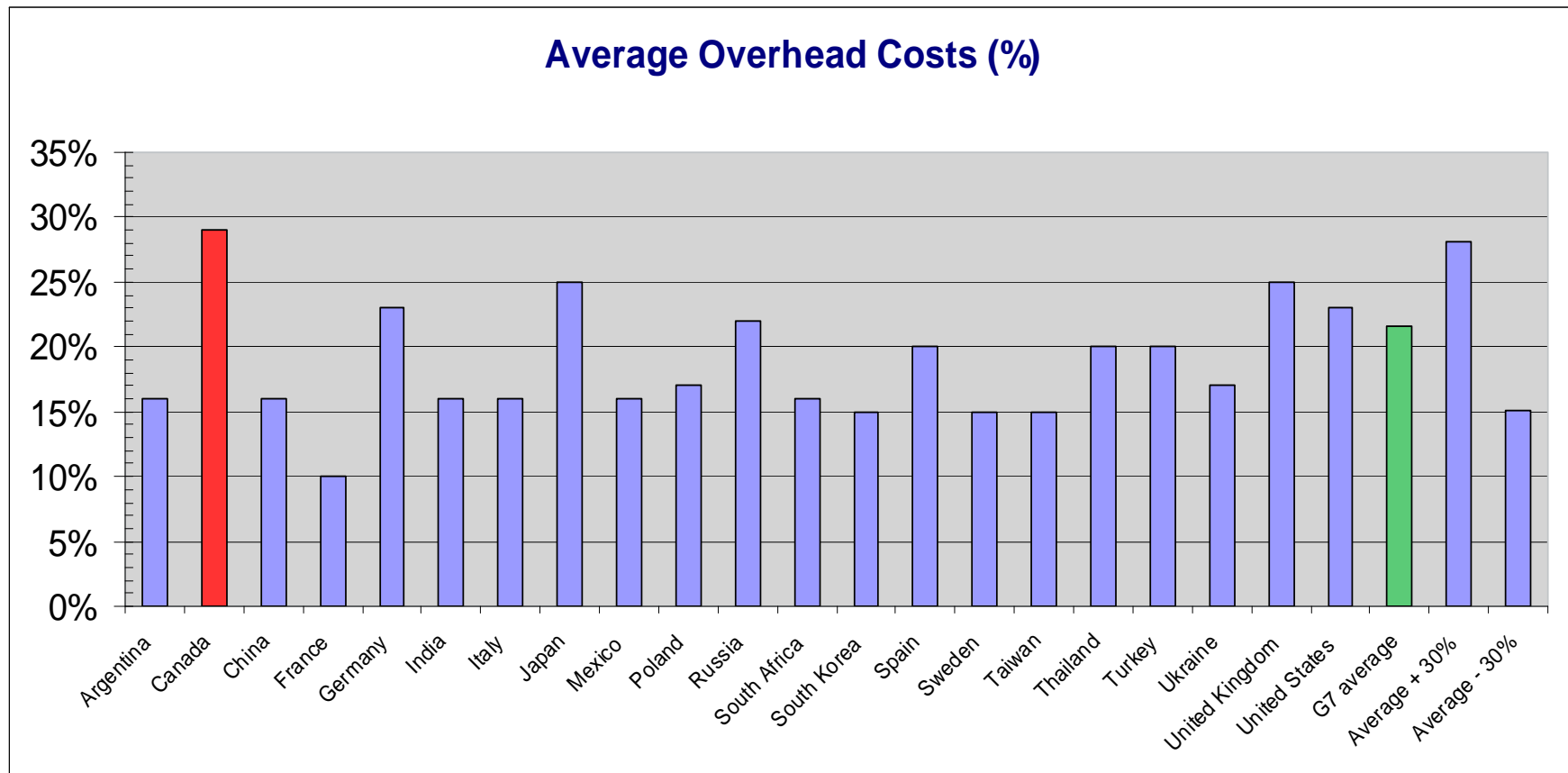
# Comparative Clinical Trial Costs/Patient



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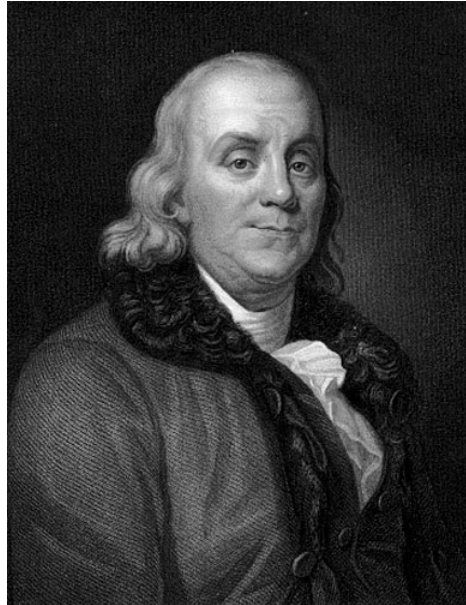
# Comparative Clinical Trial Overhead Costs/Country



# Value of Clinical Trial Investment

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**Value of Clinical Trial Investment =**  
**Procedural costs + IRB Costs + Start-up**  
**Costs + Efficiency + Quality + Speed +**  
**Complexity + Overhead costs + SR&ED**  
**Credits + Regulatory Approval Timelines**  
**+ Lost Opportunity Costs**



“We must all hang together, or assuredly we shall all hang separately.”

Benjamin Franklin



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# Backup/Alternate Slides

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