

# Three essential pillars for a more productive partnership with sponsors.

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# Many questions:

- Where is the pressure coming from?
  - What is a site made of?
  - What is changing within a site?
  - Is clinical research at risk?
  - Is a participant becoming a commodity?
- ... and some suggestions of answers

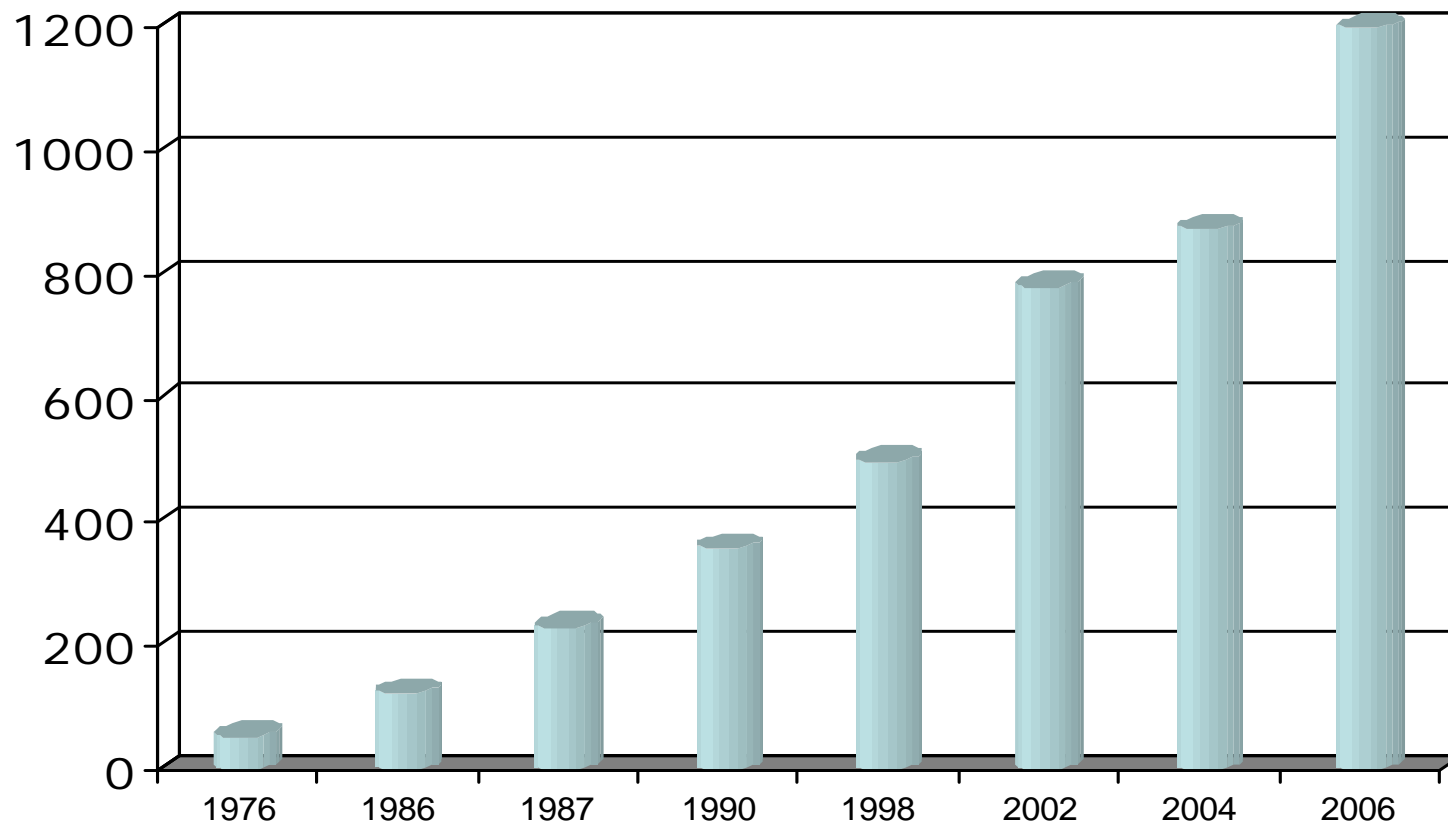
# Conclusion

Clinical Research is based on:

1. efficiency of the systems,
2. financial health, and
3. genuine interest for people.

# Where is the pressure coming from?

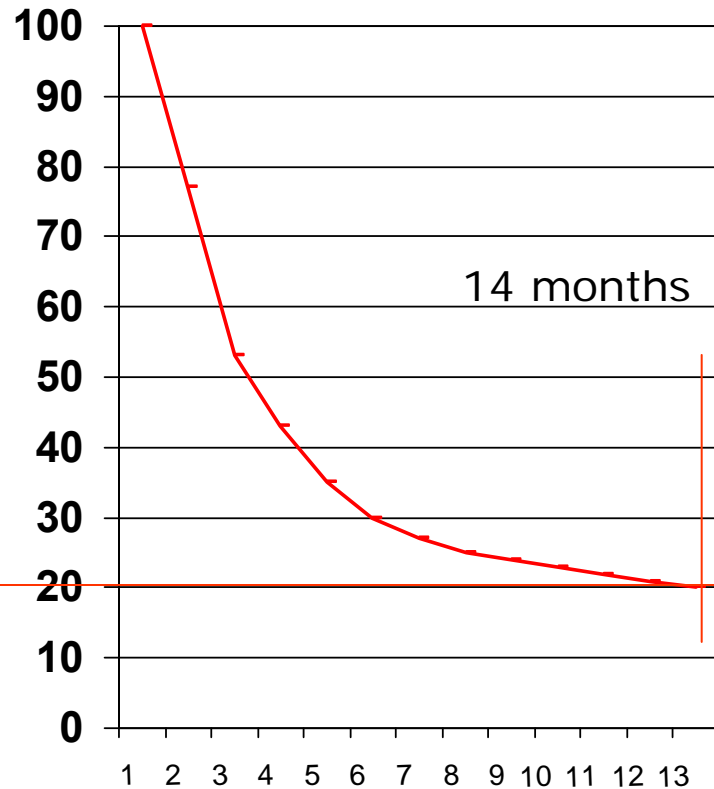
## Cost of drug development ( \$ US MM).



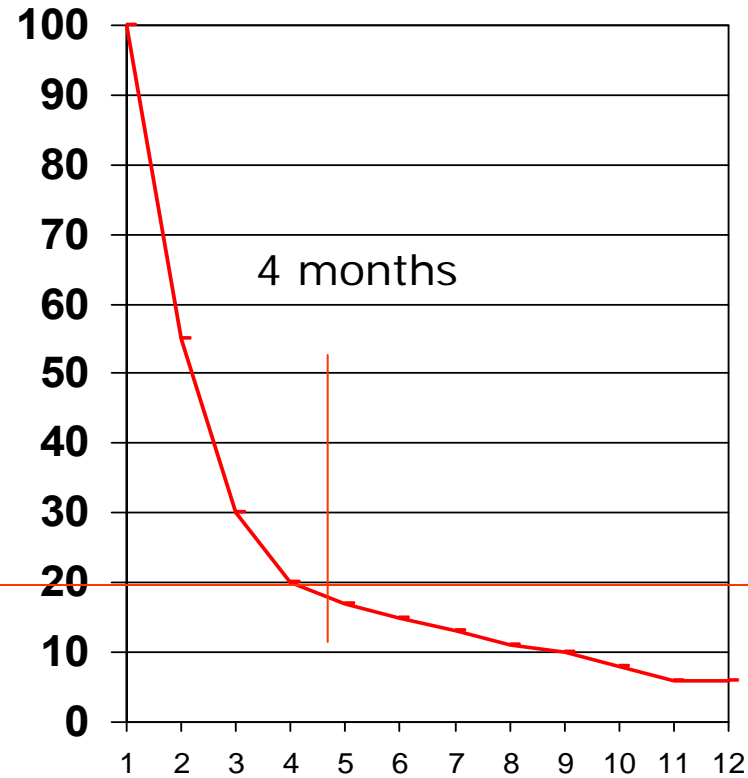
## Time to collapse

“The future is not what is used to be”

### Zantac - 1998

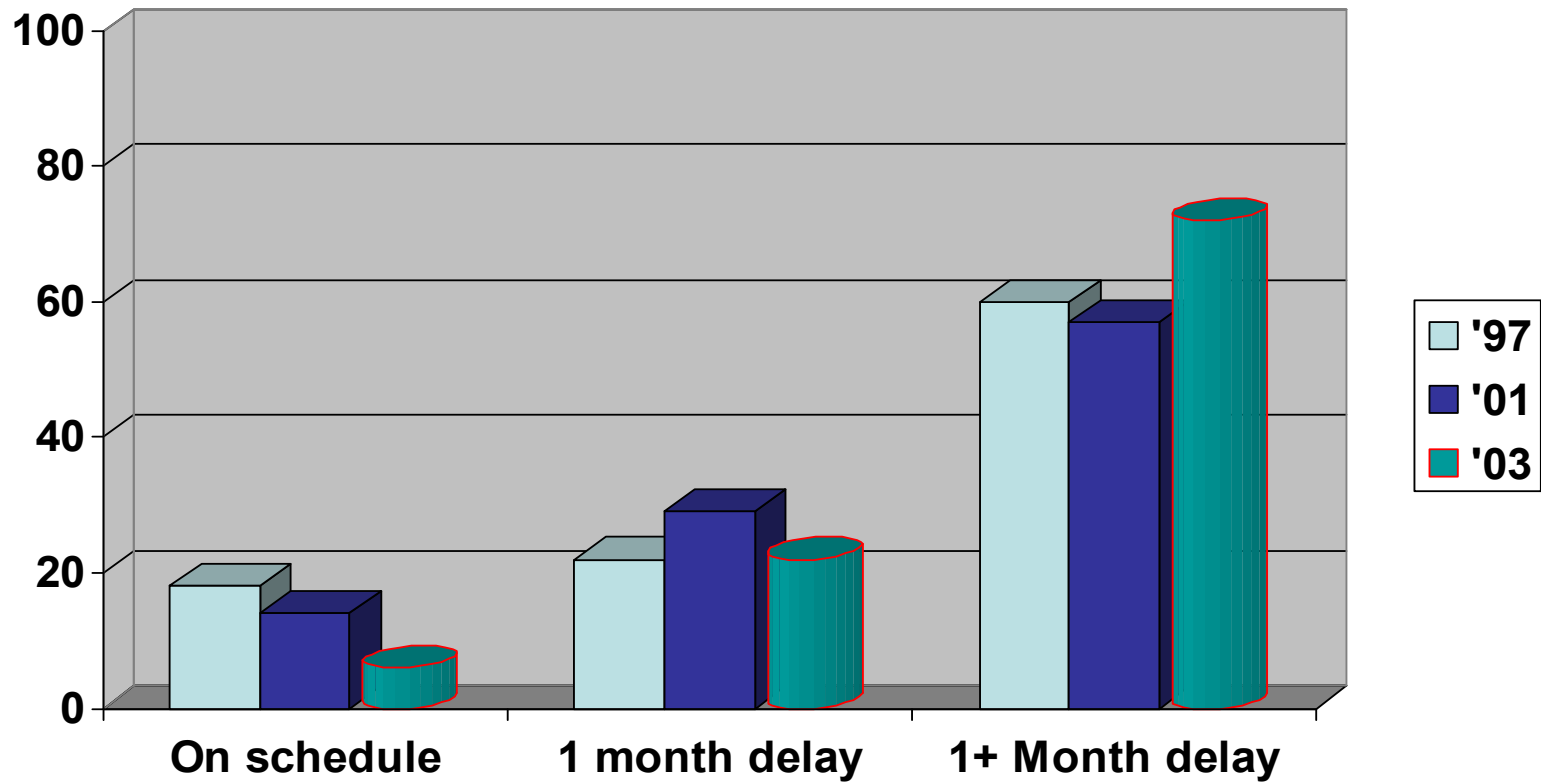


### Prozac - 2001



% of sales Vs number of months post generic

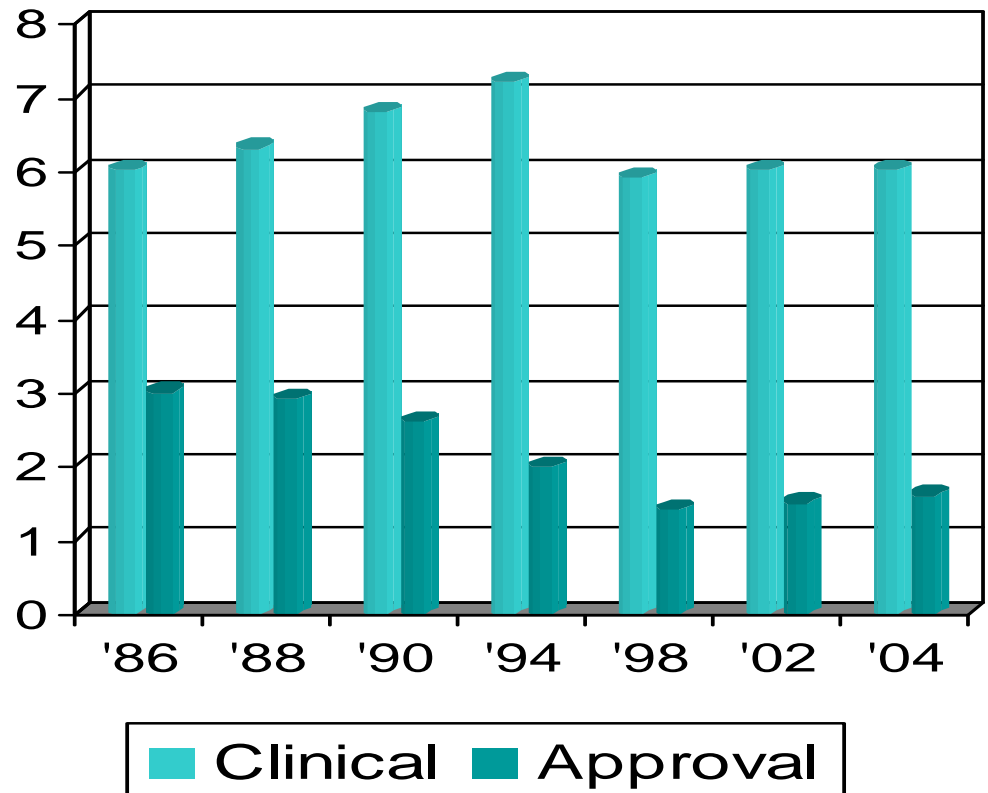
# Delays in clinical trial completion (% of trials)



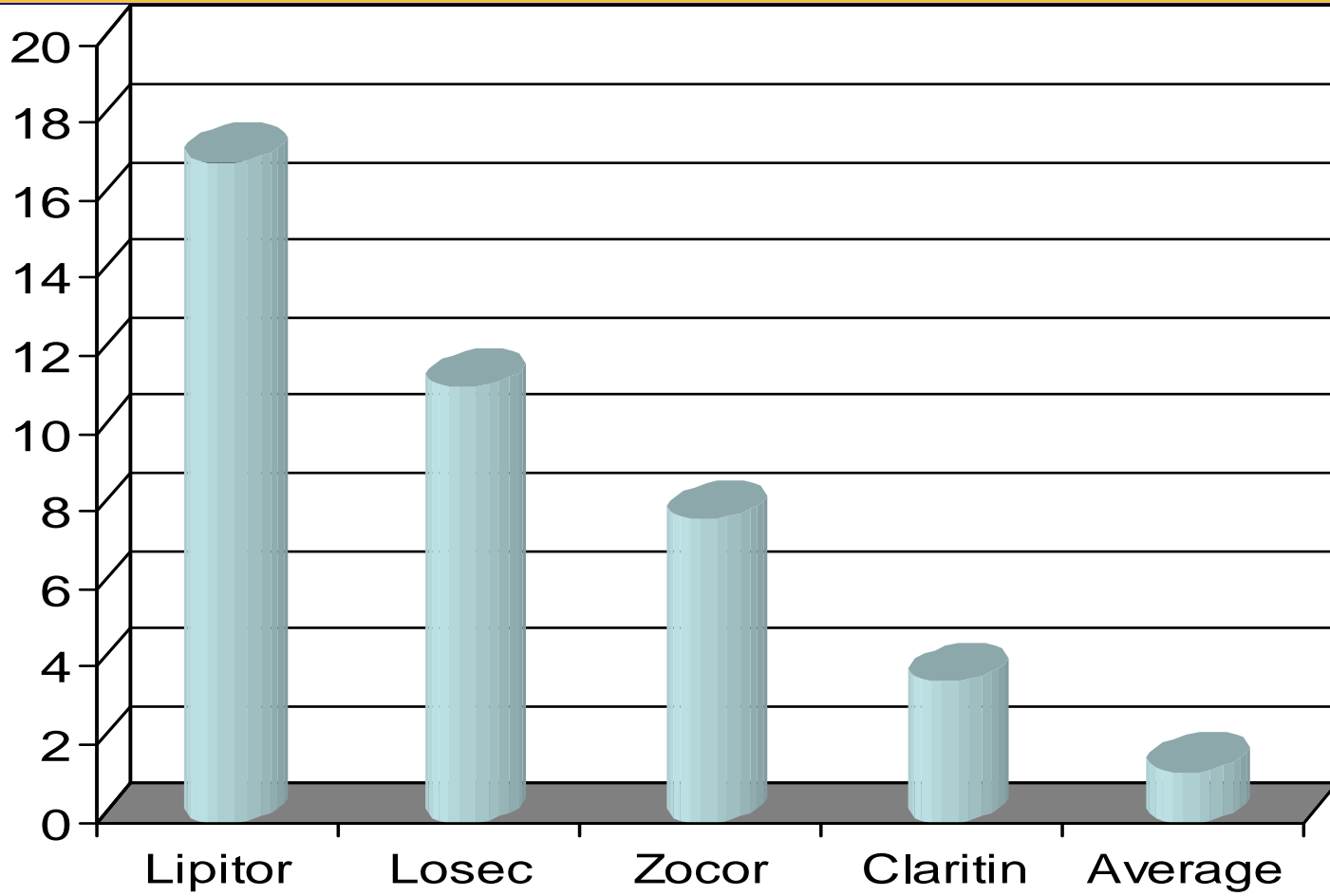
# Approval and clinical cycles

Relatively constant clinical cycle time in years but faster approval cycle time.

CenterWatch and FDA.



## Cost of a delay day (US \$MM).



Center Watch

... There is a growing load of pressure applied  
on sites and patient accrual  
but what is a site made of?

It is made of 6 key interconnected elements

## People

Participants

Nurses

Physicians

## Systems

Projects & Protocols

Work

## Finances

Budget & Cash flow

This is a **changing** environment.

# ... is made of nurses

- «Must have» qualities
  - Caring personality
  - Well integrated nursing and medical knowledge
  - Organised and structured mind... but also flexible
  - A «Make it Happen!» mentality
  - A «Sixth Sense» for problems
  - Bilingualism
  - **Understanding roles and responsibilities**
    - i.e. managing / directing a trial
      - CRO / Sponsor / Site management / PI / Auditor
  - **Computer literate**

## ... is made of physicians

- Dedicated research time
- **Clinical research set up**
  - changing from “amateur” to “professional”
- **Much more attractive “Plan B”**
- **> 50% of US physicians will do only 1 trial.**
- **Lack of Investigators in '08-'09 ?**

# ... is made of participants

## Unpopularity contest

% of US adults who think companies "generally do a good job of serving their consumers"



Source: Harris Interactive

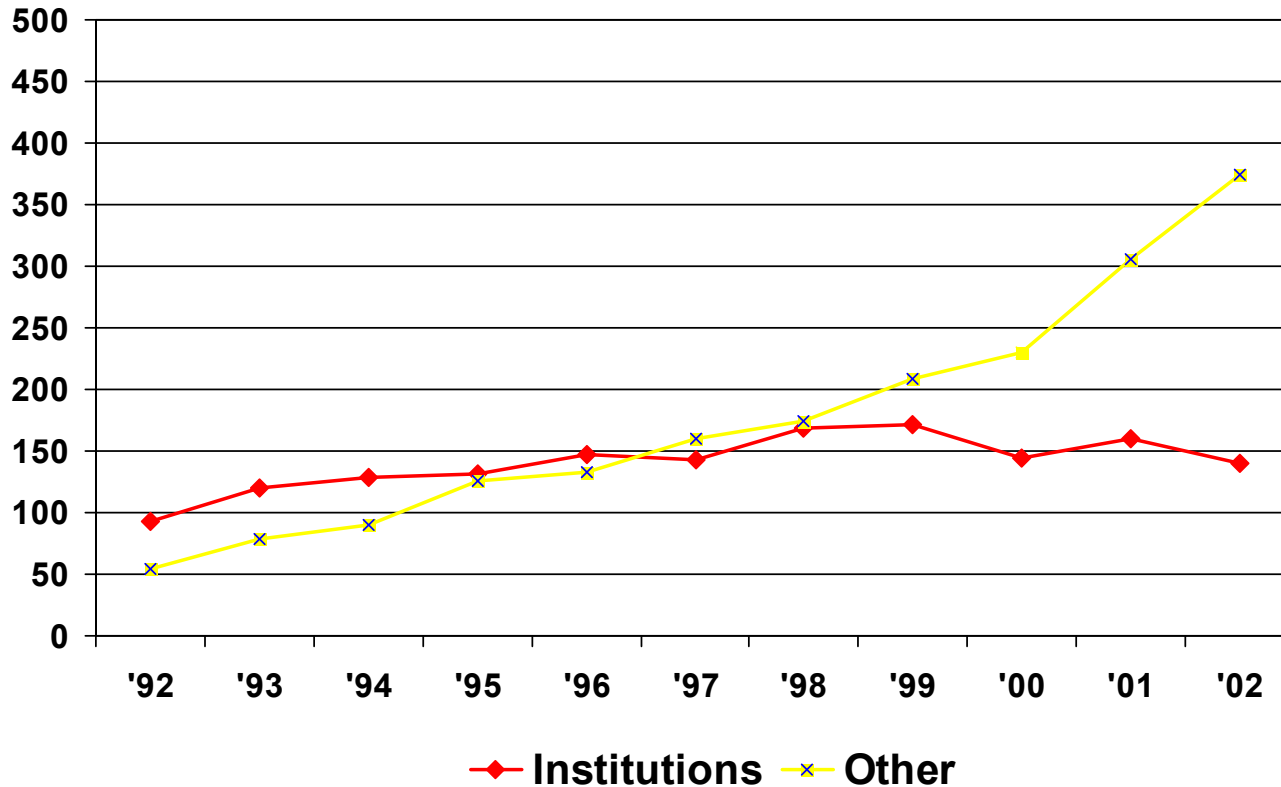
# ...is made of participants



# ... is made of projects

- Patient accrual
  - on time
  - with competitive pricing.
    - One “case” in US = 1.0 \$
    - In Canada = 0.87 \$
    - **In China = 0.18 \$**
- Where are the projects going to?

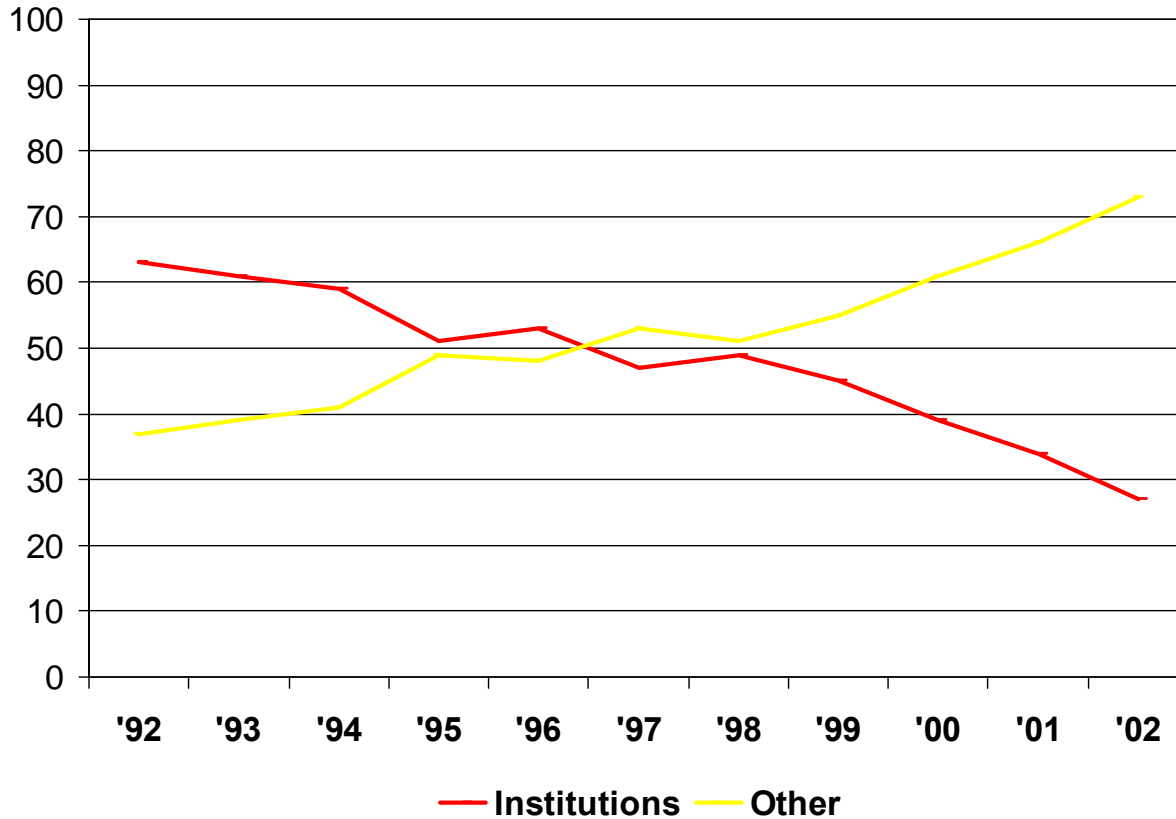
# Canada Clinical Research Investment (MM\$) 1992 to 2002



Source: PMPRB, annual reports 1992 to 2002.

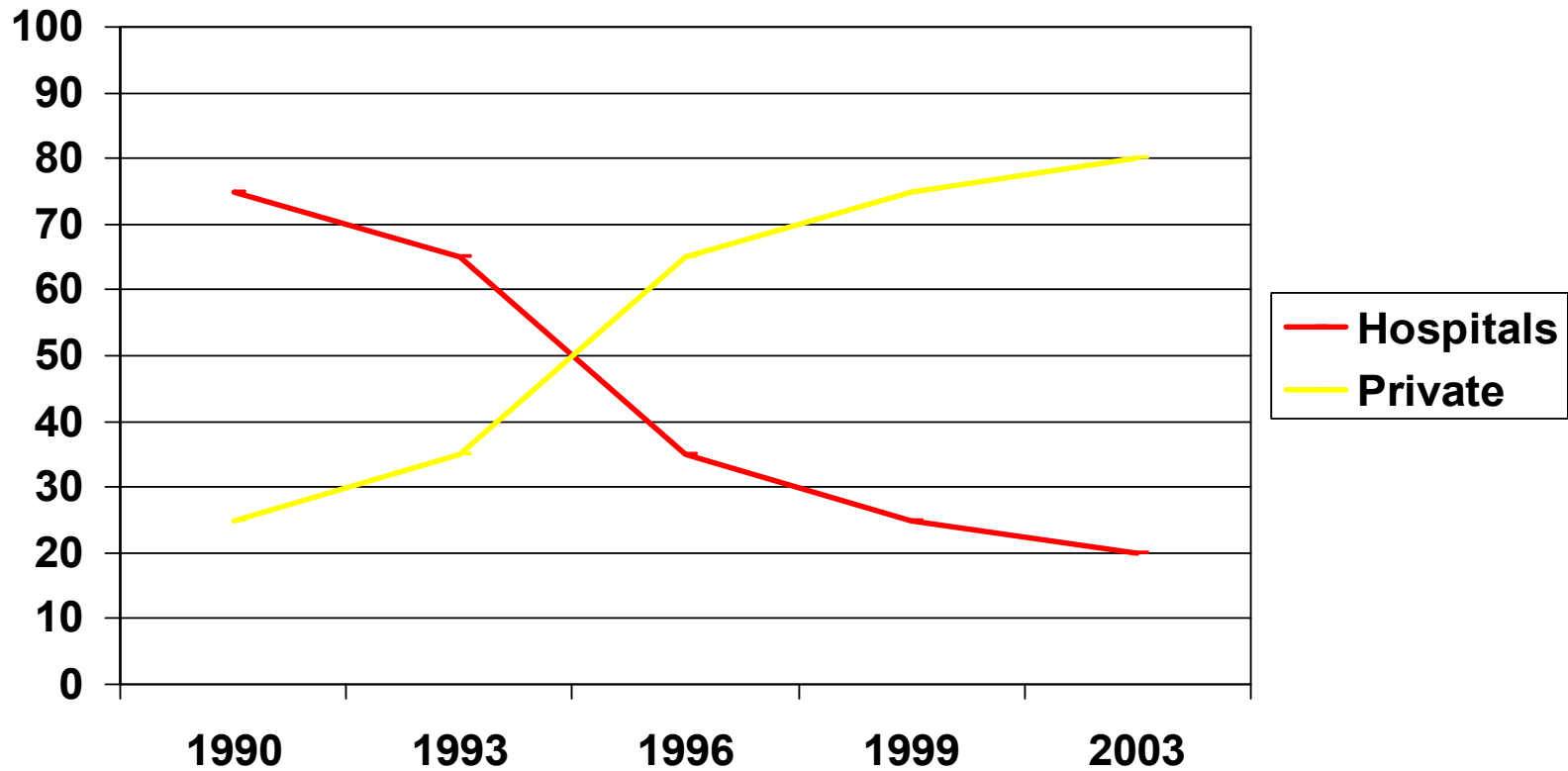
# Percentage of Clinical \$ in Canada

1992-2002

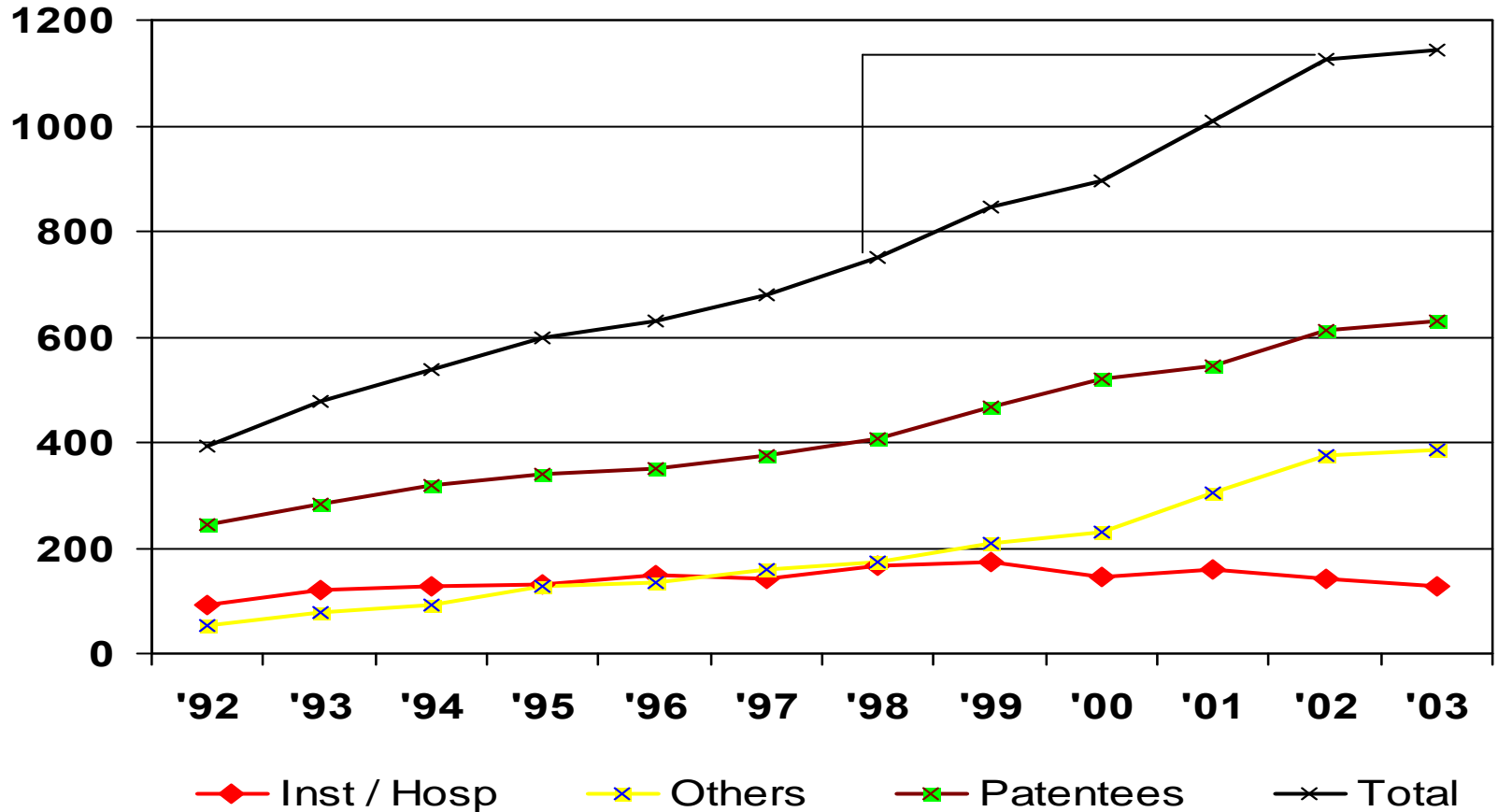


Source: PMPRB annual reports 1992 à 2002.

# Percentage of Clinical \$ in US 1990-2003

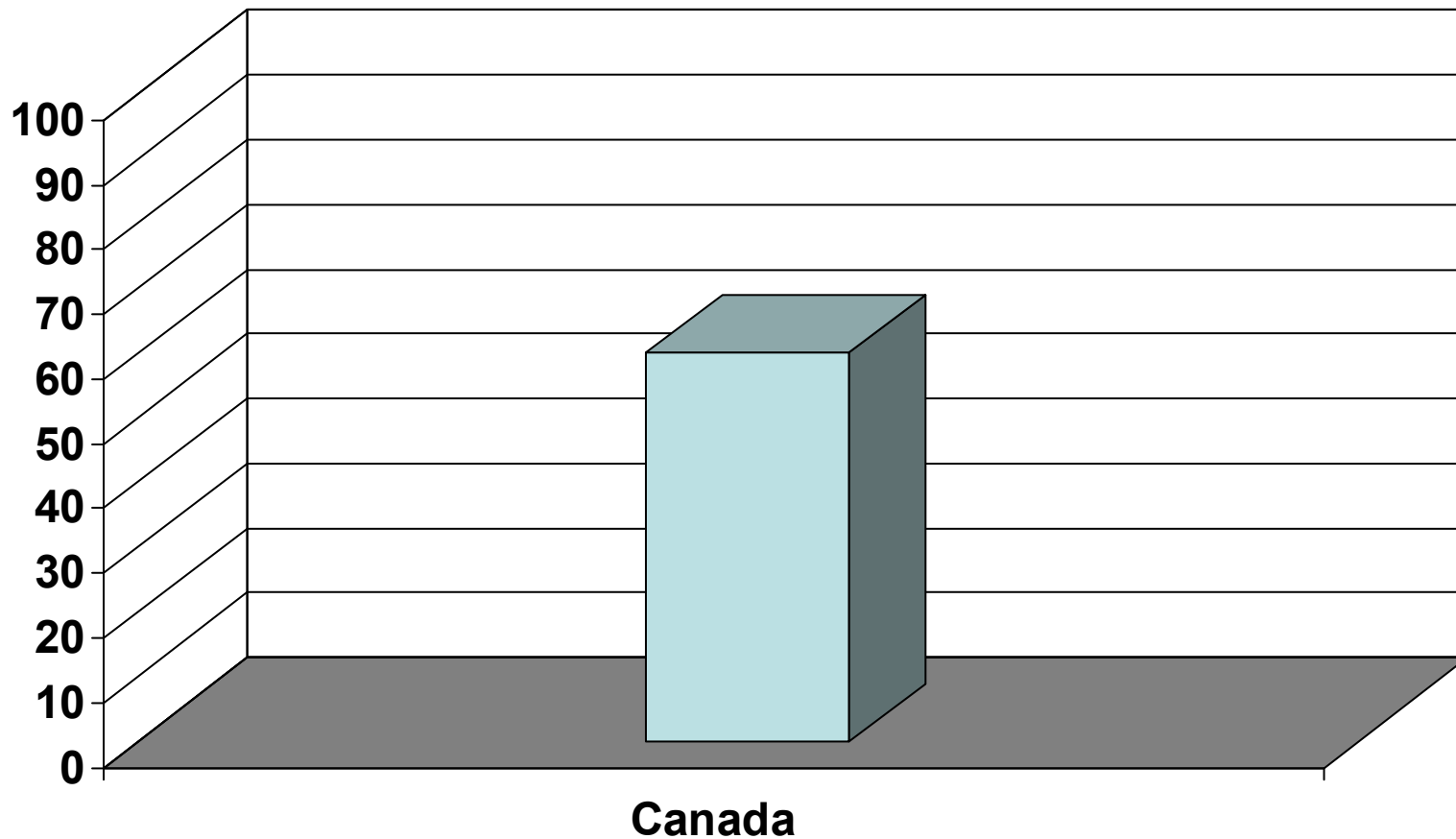


# Canada Clinical Research Investment (MM\$) 1992 to 2003



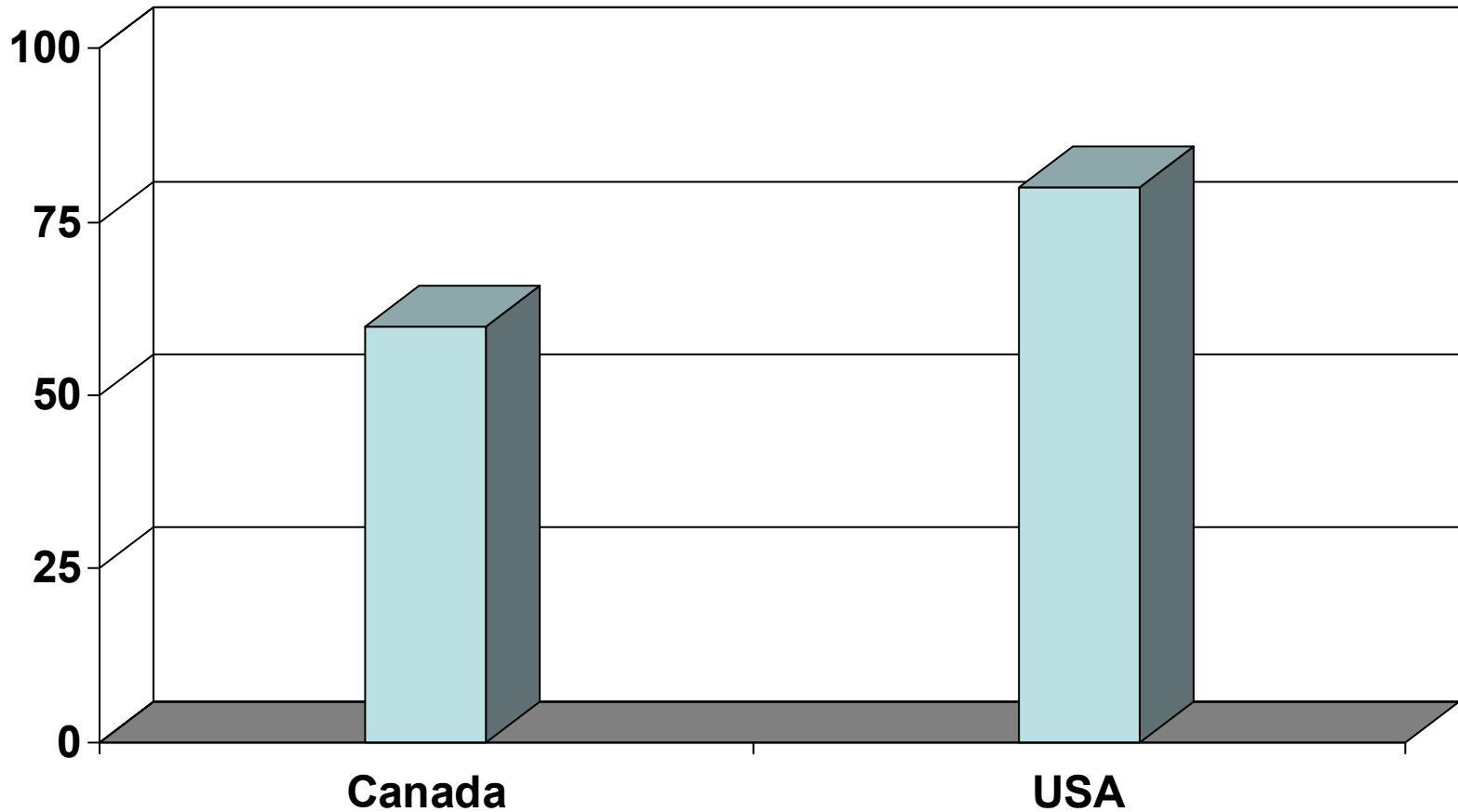
# Research Investment Growth (%)

1998 - 2003



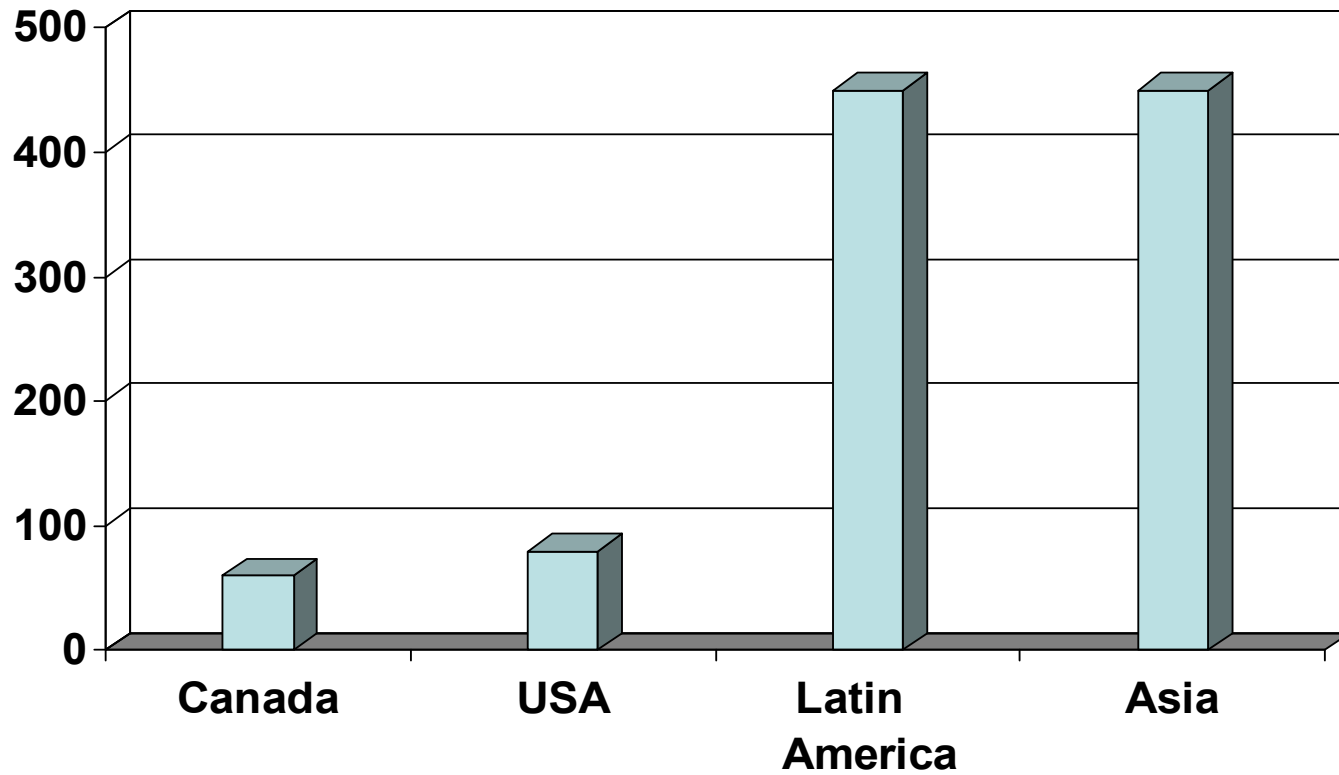
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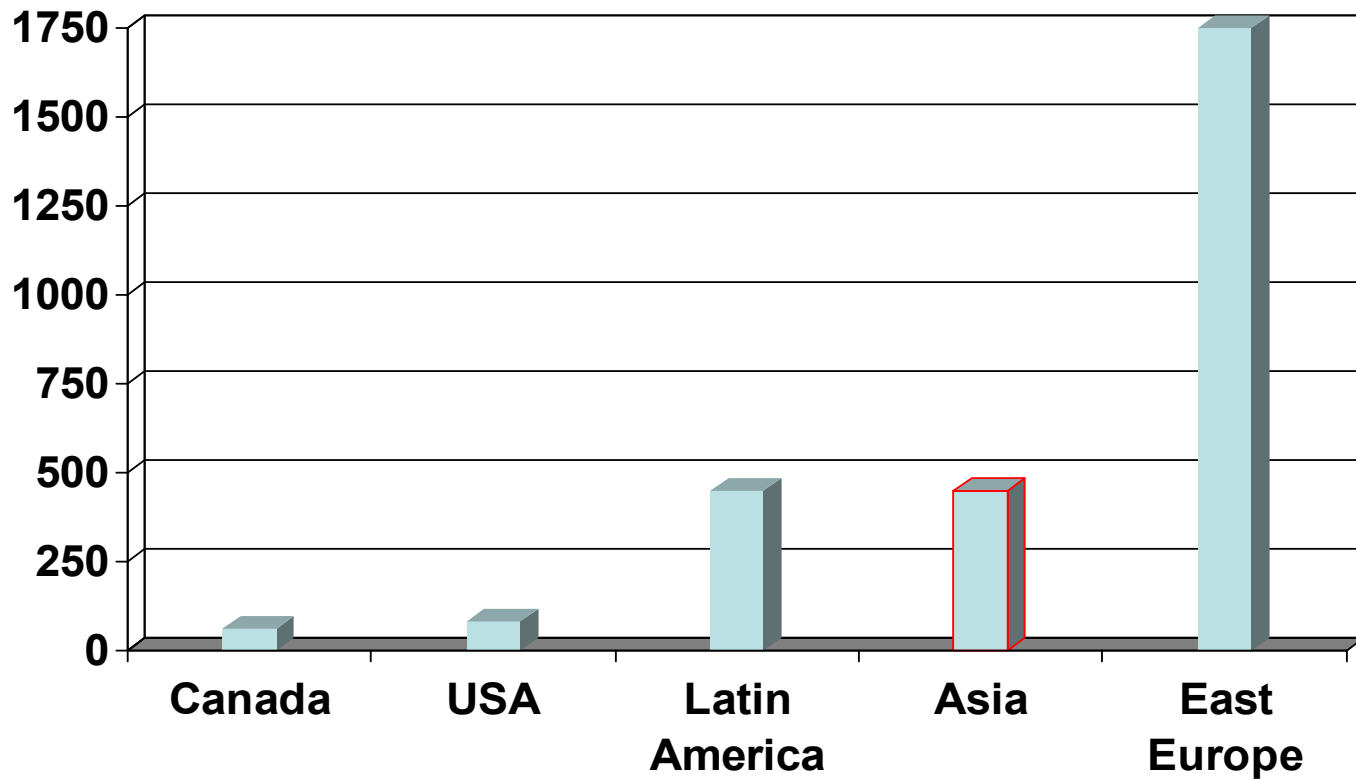
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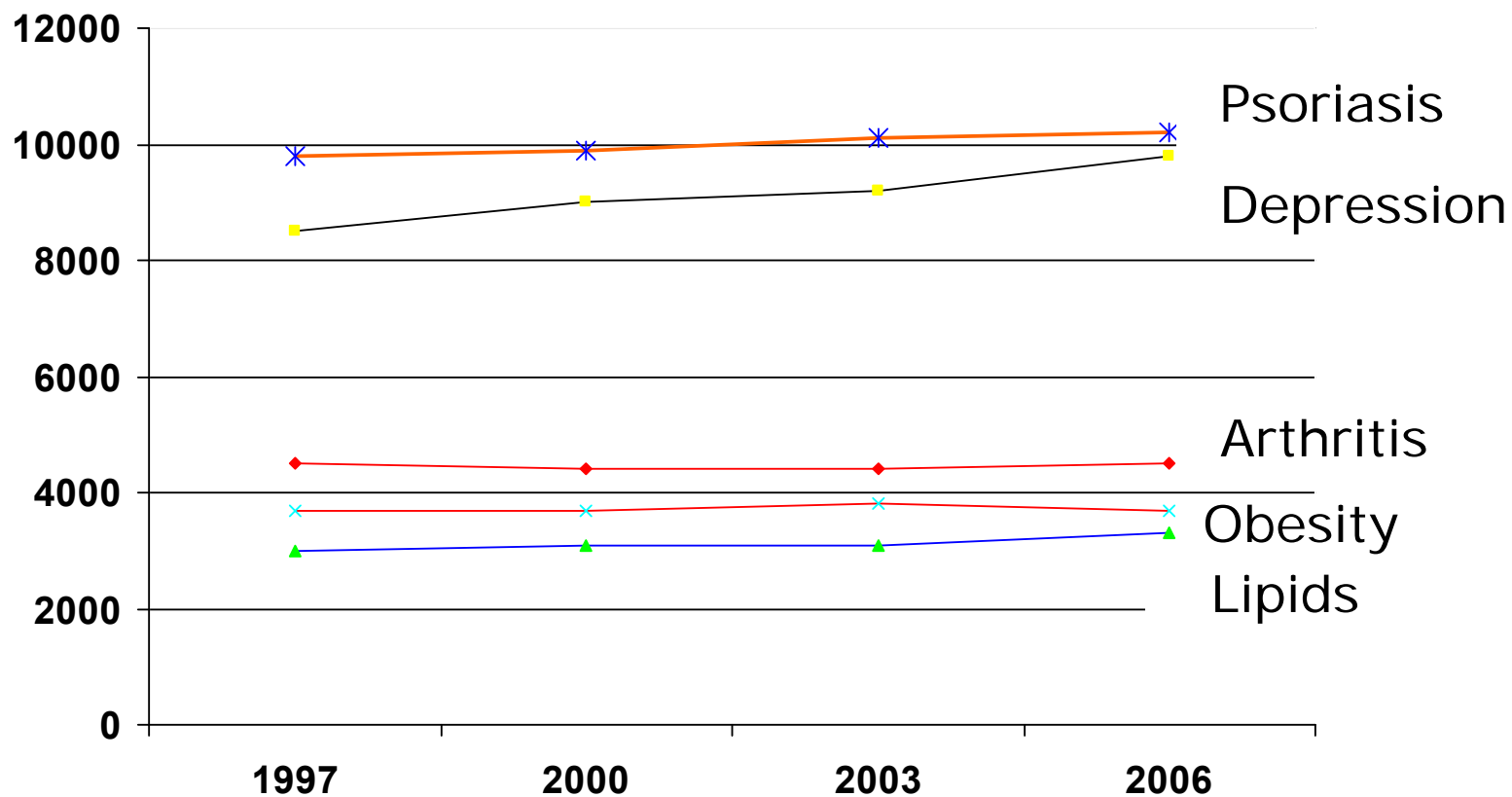


**... is made of work**

**...and a lot of it:**

- Staff management**
- Finance management**
- Business development**

# ... is made of budgets comparative budgets from '97 to '06

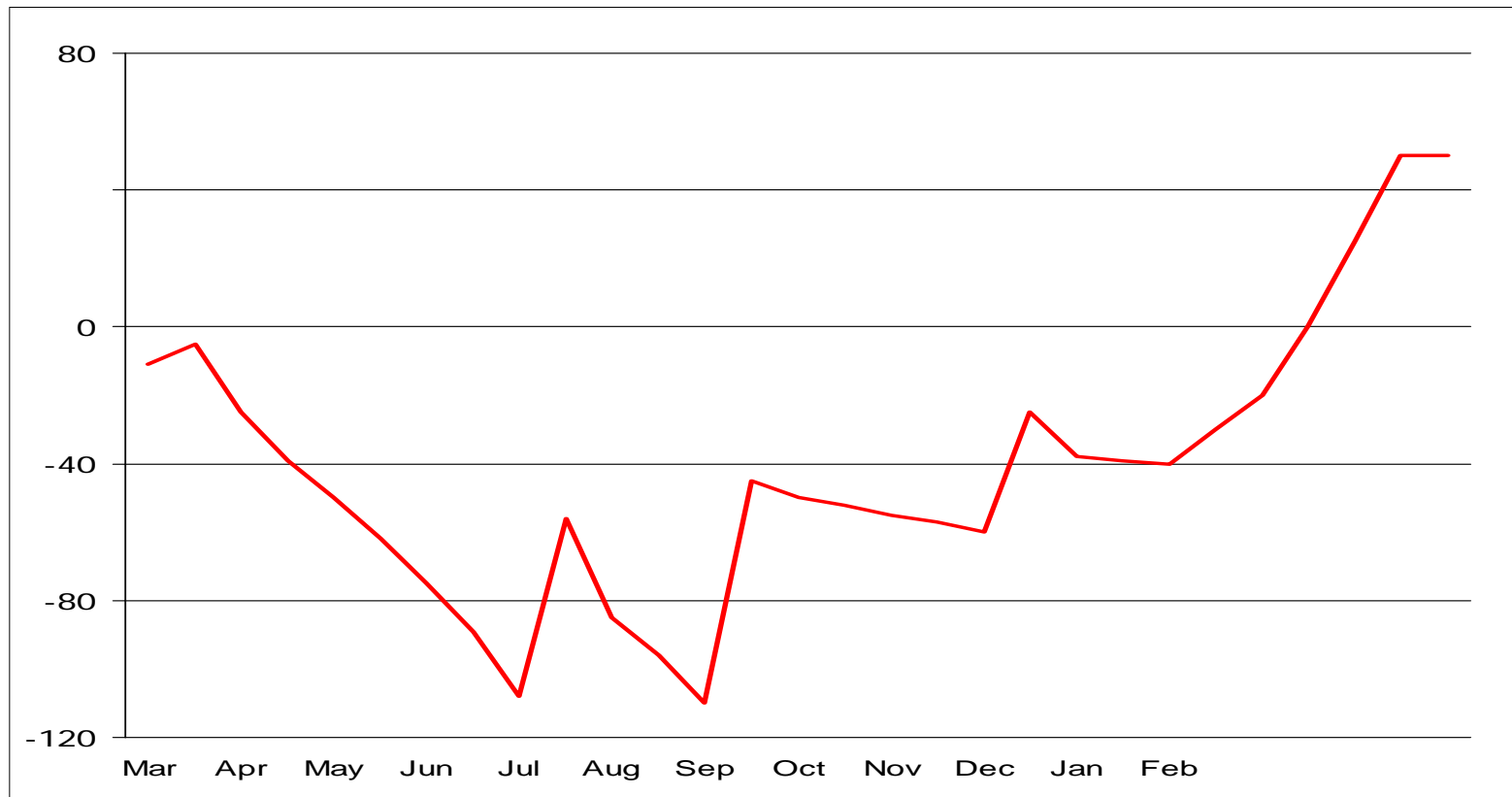


## ...is made of protocols

- of increasing complexity,
- with more visits,
- with more procedures,
- with more documentation,
  - SOP, archive, “study binder”, ...
- with new roles, such as data entry (RDE),
- with more hidden costs:
  - SAE reporting
  - Amendment (s...)
  - Data lock, data queries, deadlines, etc
- with more reluctant patients.

# ... is made of finance - Cash Flow and Payment Terms

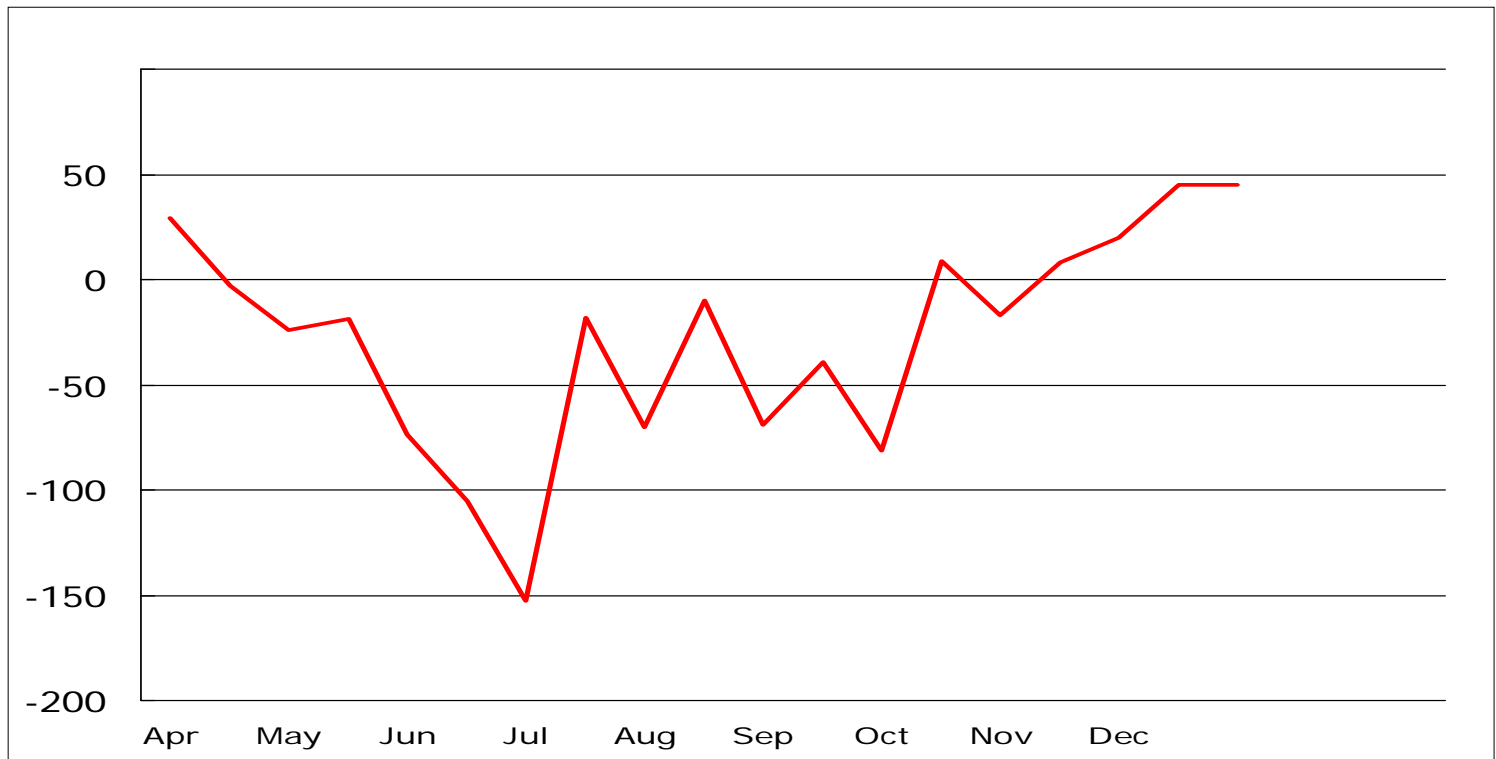
**\$8,000 per completed case, 10% down payment, Quarterly payments**



Cumulative value of procedures ( \$ ,000 )

## ... is made of finance - Cash Flow and Payment Terms

**\$8,000 per completed case, 10% down payment, Monthly payments**



Cumulative value of procedures ( \$ ,000 )

## Payment terms $\neq$ payment schedule

- **Payments on time** (as of contract) :
  - 90 % of payments are late by 15 days or more
  - 50 % of payments are late 30 days or more
  - 15 % of payments are late 60 days or more

## Initial payment

<b>Year</b>	<b>Total projected</b>	<b>Down payment</b>
1998	\$ 300,000	\$ 100,000
2003	\$ 400,000	\$ 12,000
2006	\$ 600,000	\$ 1,500

# Strategies and practices

Sponsors ought to look at:

- Budget
  - Account for out of budget expenses
    - SAEs
    - Amendments
    - RDE
- Payment terms
  - Adopt bridges between RDE and payments
  - Monthly and **on time**
- Incorporate quality metrics in budgets
- Effective e-meetings
- Back to GORP

# GORP: Good Old Reliable Project

- Final and clear protocol at study start
- Patients likely to exist
- Complete, clear & final CRF
- Productive Investigator meeting
- CRA well trained
- Attention to data VS details
- Empowered CRAs
- Realistic timelines
- Study drug on time
- Communication channel
- Consistent directives
- Budget at PICAS 70 (with corresponding requirements)
- Payment schedule

# Strategies and practices

Sites ought to:

- Adopt business responses to business pressures
- Adopt new technologies faster
- Provide robust feasibility assessments
- ... and deliver on the promises
- Be professionals
  - Training, accreditation
- Create partnership with sponsors and hospitals

## **But the essential must remain:**

1. quality of the systems,
2. financial health, and
3. genuine interest for people.

**Anything less will put at risk the  
integrity of clinical research.**