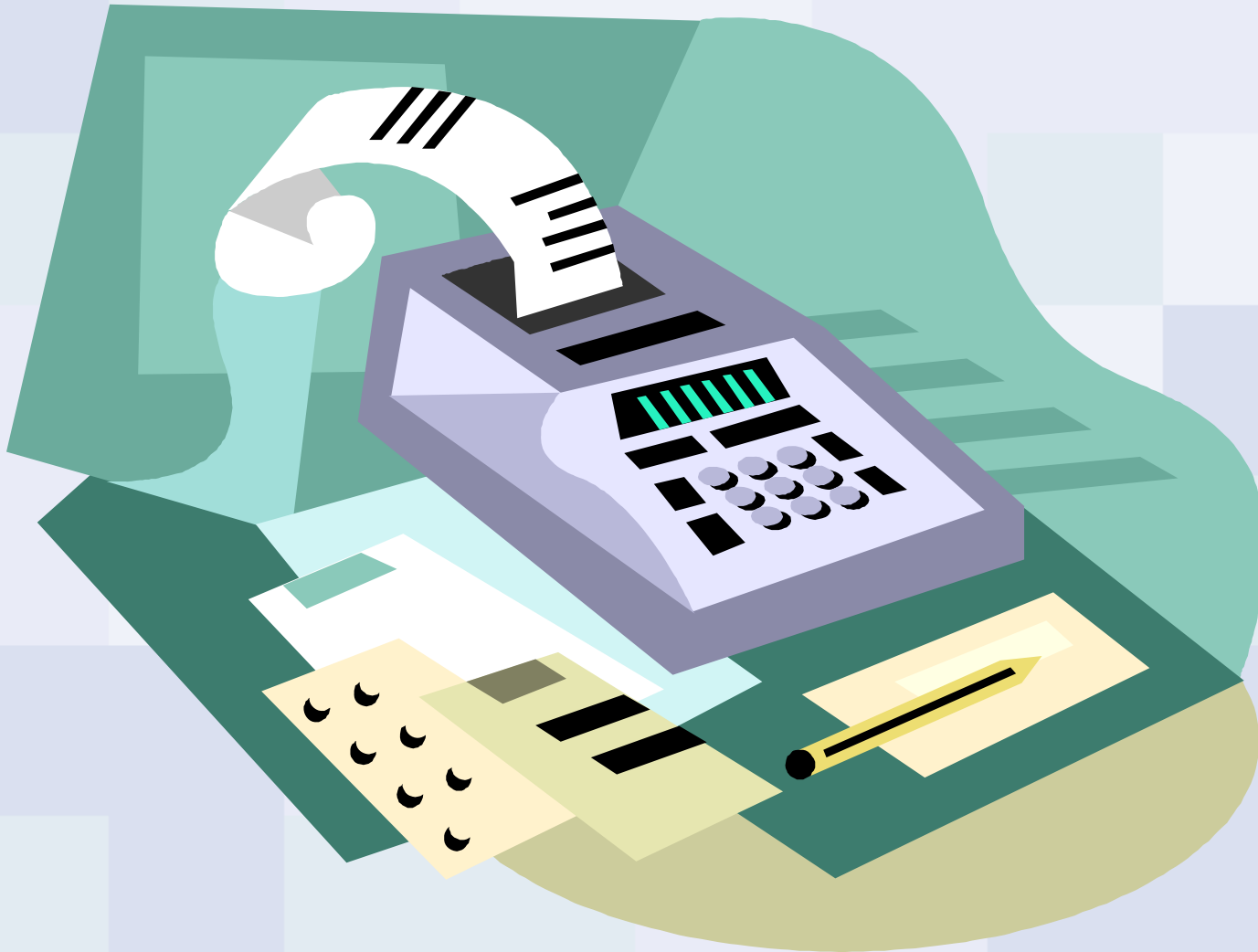


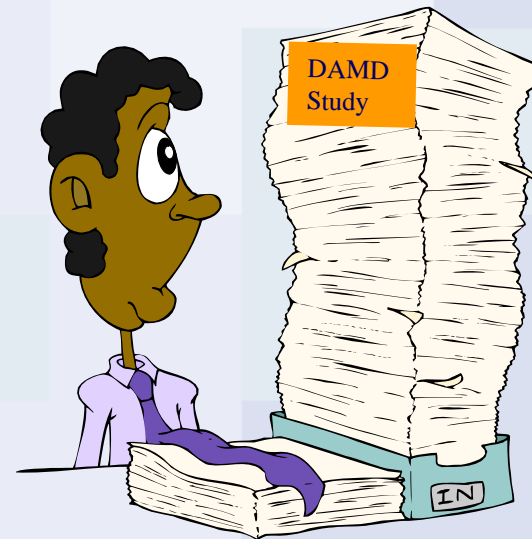
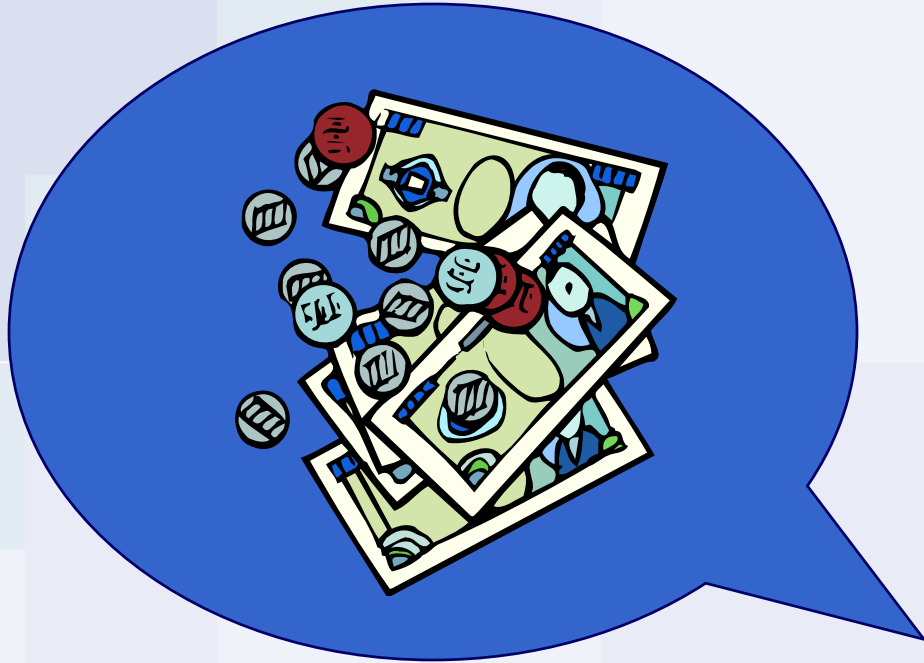


# Developing the Investigator Budget



Our business is science. Our product is life.

# How do we get from Protocol to Budget?





# Investigator Budget Template D.A.M.D. Study

QLT Payable Procedures and Services	Cost/ Test	Baseline Visit	V2 Day 1	V3 Day 2	V4 Day 7	V5 Day 14	V6 Day 21	Telephone Follow Up	Final Follow Up	Total Proced.	Total Procед. Costs
<b>Laboratory Tests</b>											
PK Tests		1	1	1	1	1				5	
Drug Screen		1								1	
Pregnancy Test		1								1	
Hematology and Chemistry		1	1		1	1	1		1	6	
Virology		1								1	
Urinalysis		1								1	
<b>Procedures</b>											
Vital Signs		1	1	1	1	1	1		1	7	
Physical Examination and Med Hx		1								1	
ECG		1	1		1	1	1		1	6	
Chest X-Ray		1								1	
<b>Study Treatment</b>											
Study Drug Administration and Accountability			1	1	1	1	1			5	
<b>Labour Charges</b>											
Investigator (hours)		3	2	2	2	2	2	0.5	2	14	
Nurse/Research Coordinator (hours)		7	4	4	4	4	4	3	4	30	
***Study Management (hours)		4	2	2	2	2	2	2	3	16	
<b>COST/VISIT</b>	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -		
Overhead on Procedures and Services @ 25%		-	-	-	-	-	-	-	-		-
<b>Miscellaneous Charges</b>											
Patient Expenses		1	1	1	1	1	1		1		\$ -
Courier / Mail / Incidentals											
<b>TOTAL COST PER VISIT</b>		<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>		<b>\$0.00</b>		

\*\*\*Includes maintenance of regulatory binder, IRB submissions, SAE reporting, patient contact etc.

# The Numbers

## Various sources for figures:

- Internet
  - <http://www.ama-assn.org/>
- Software program
  - Medicare Fee Calculator
- Historical – previous trials
- Experts and consultants





# More Numbers...

The screenshot shows a search results page for CPT codes. The browser window title is "CPT Online - Microsoft Internet Explorer". The address bar shows the URL: [https://webstore.ama-assn.org/search/CptLookupResultsPage.html;sessionid\\$3G4IHAADVNGJTLA0MQGRNWQ?\\_requestid=83626](https://webstore.ama-assn.org/search/CptLookupResultsPage.html;sessionid$3G4IHAADVNGJTLA0MQGRNWQ?_requestid=83626). The page displays two search results:

CPT Code	Description	Rate 1	Rate 2
99244	Office consultation for a new or established patient, which requires these three key components: a comprehensive <b>history</b> ; a comprehensive examination; and <b>medical</b> decision making of moderate complexity. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Physicians typically spend 60 minutes face-to-face with the patient and/or family. <a href="#">CPT Assistant, Volume 13, Issue 10, October 2003</a> <a href="#">CPT Assistant, Volume 12, Issue 9, September 2002</a> <a href="#">CPT Assistant, Volume 12, Issue 7, July 2002</a> <a href="#">CPT Assistant, Volume 11, Issue 8, August 2001</a> <a href="#">CPT Assistant, Volume 02, Issue 1, Spring 1992</a>	\$149.47	\$121.11
99245	Office consultation for a new or established patient, which requires these three key components: a comprehensive <b>history</b> ; a comprehensive examination; and <b>medical</b> decision making of high complexity. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Physicians typically spend 80 minutes face-to-face with the patient and/or family. <a href="#">CPT Assistant, Volume 12, Issue 9, September 2002</a> <a href="#">CPT Assistant, Volume 12, Issue 7, July 2002</a> <a href="#">CPT Assistant, Volume 11, Issue 8, August 2001</a> <a href="#">CPT Assistant, Volume 07, Issue 10, October 1997</a> <a href="#">CPT Assistant, Volume 03, Issue 1, Spring 1993</a> <a href="#">CPT Assistant, Volume 02, Issue 1, Spring 1992</a>	\$193.62	\$160.91



# The Numbers...

**Medicare Fee Calculator 2003**

File Colors Tools

Code: **99245** (Office consultation)

Medicare Locality: NY 00803-01 MANHATTAN, NY

Conversion Factor Calculations

Name	ConvFact	Adjusted	Unadjust
RBRVS Non-Fac Units	1	7.11	5.88
*			

Physician Fee

Code	Non-Facility		Facility		Non-Par
	Fee	Units	Fee	Units	NF Charge
99245	257.49	7.11	209.07	5.78	281.31

DME Fee (1st Qtr)

MOD	JURIS	Ceiling	Floor	Fee
		0	0	0

Laboratory Fee

MOD	National Limitation		60% Median	60% Fee
	60%	62%		
	0	0	0	0



## In addition.....

### Study Start Up Fee

- ✓ Contract and grant negotiation
- ✓ IRB submission, set up study files

### Study Management Activities

- ✓ SAE reporting
- ✓ Maintain Investigator Binder
- ✓ Patient contact and follow up
- ✓ Study amendments



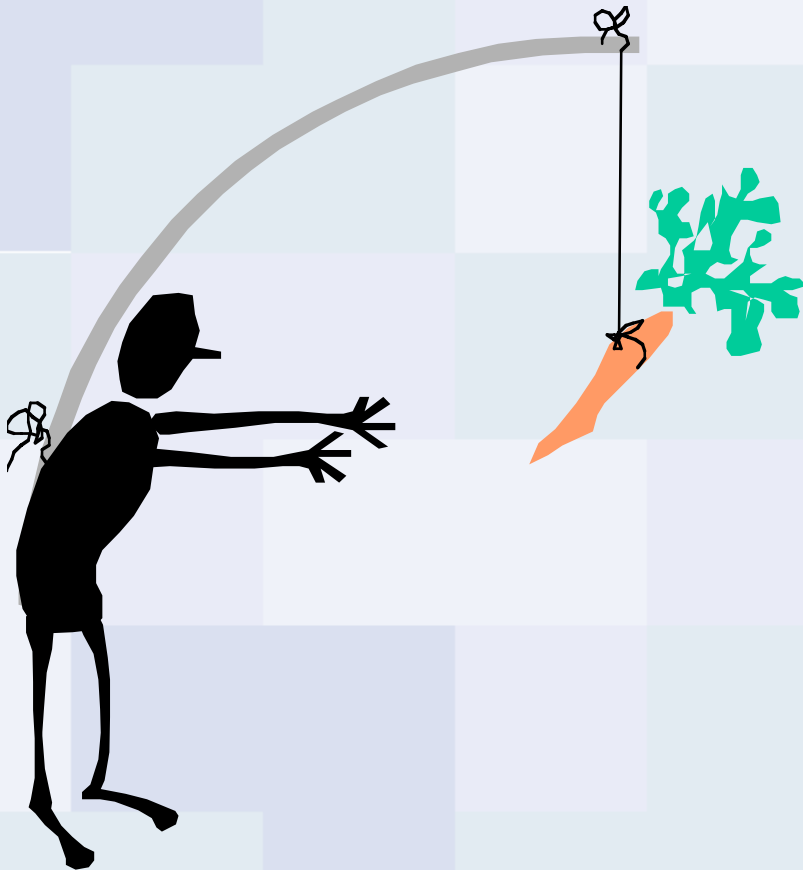


# Investigator Budget Template D.A.M.D. Study

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Overhead on Procedures and Services @ 25%		-	-	-	-	-	-	-	-		-
<b>Miscellaneous Charges</b>											
Patient Expenses		1	1	1	1	1	1		1		\$ -
Courier / Mail / Incidentals											
<b>TOTAL COST PER VISIT</b>		<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>		<b>\$0.00</b>		

\*\*\*Includes maintenance of regulatory binder, IRB submissions, SAE reporting, patient contact etc.

## More Things to Consider....



### Sponsor Activities

- 🕒 monitoring
- 🕒 queries
- 🕒 contacts - phone, meetings

### Audit / Inspection

- 🕒 time spent in preparation
- 🕒 time spent during event
- 🕒 follow up activities



# Payment



Our business is science. Our product is life.



## Payment Structure

- \$ Start up payment made upon signature of agreement
- \$ Quarterly payment for “work done” during the quarter (amount owed - 10%)
- \$ Final payment = sum of 10% holdbacks





# Pass Through Expenses

**Reimbursed by QLT Inc, but not part of the Investigator Budget:**

- **IRB Fees**
- **Local Advertising**
- **Screen Failures**
- **Pharmacy Fees**
- **Document Storage**

# Secretive drug trials questioned

## First in a series

Stories by Margaret Munro  
CanWest News Service

Canadian human-research subjects are an increasingly sought-after commodity in a \$1-billion drug-testing industry that recruits patients by the head.

Seniors with dementia are testing pills designed to slow mental decline. Heart-attack victims are signing on to test new clot-busting drugs. And a growing number of Canadians are responding to newspaper and Internet ads recruiting volunteers to try new treatments for everything from arthritis to flagging sex drive.

Testing medicines on human volunteers is an essential stage in developing new, potentially lifesaving drugs. Animal testing can only go so far and drugs must be tested on humans — and lots of them — before they can be allowed on the market.

But a four-month CanWest News Service investigation has found that research companies are pressuring Canadian doctors to enrol patients quickly into trials, engaging in questionable recruiting practices and are at times conducting trials that are not ethically or scientifically sound.



are supposed to protect trial volunteers, have been caught cutting corners and reprimanded for not properly warning patients of the risks involved in trials.

One major Canadian university for years broke federal ethics rules and failed to warn patients of all the dangers and side-effects associated with its medical experiments and drug trials.

In some trials, doctors are little more than middlemen who sign up patients and provide the drug being tested. They then have to provide patient queries, collect and analyze the data, and write the trial reports.

Physicians are typically paid \$1,000 to \$5,000 per patient enrolled in a trial, compensation seldom declared to the patients swallowing the pills.

Some physicians and academics who have built careers doing research for drug companies can pull in as much as \$300,000 a year.

Prof. Trudo Lenters, a lawyer at the University of Toronto, says "barbers' fees" for recruiting patients are now commonplace, even though they are seldom described as such.

The fees are typically integrated into per-patient payments to doctors



Newspaper ads are used to recruit subjects for clinical tests.

and doctors are often told their participation in trials will help lead to new knowledge.

where data that might have harmed the sales of certain drugs has been suppressed.

trated," says Dr. Yves Lacourcière, the Quebec City-based principal investigator for the Carvelian arm of the trial.

Detailed information on clinical trials under way in Canada and the per-patient fees paid for specific trials is hard to come by. The deals signed between research companies, doctors, and universities are secret.

But a report prepared for the federal government last year estimated between \$800 million and \$1 billion is spent on clinical trials in Canada each year — making it the largest pot of medical-research funding in the country.

Health Canada, federal research councils, the pharmaceutical industry, universities, medical associations, and the National Council on Ethics in Human Research all have rules about clinical trials.

Those rules state that trials must be scientifically and ethically sound; patients cannot be coerced or misled into joining trials; they must be clearly told the risks; doctors should be properly trained to run trials and not paid excessive fees for recruiting patients.

But not nearly enough is done to ensure the rules are followed, says Prof. Michael McDonald, an ethicist at the University of B.C.

He headed a Law Commission of Canada study that in 2000 pointed to major problems with the system meant to ensure protection of Canadians volunteering for trials. McDonald and many of his colleagues are the secretive industry critics out for better oversight.

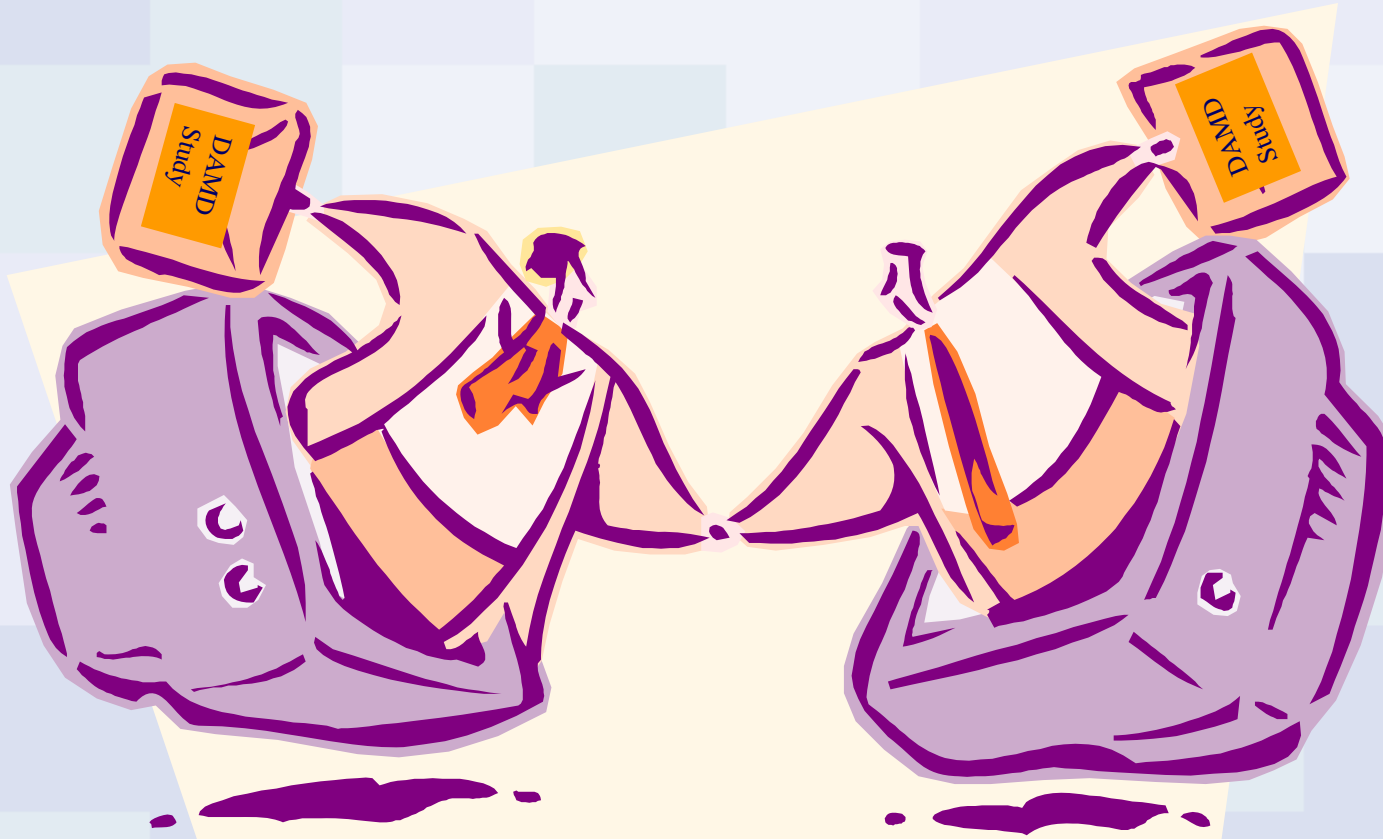
Canadians, they say, deserve a more transparent and fair system



McDONALD



At the end of the day...



Our business is science. Our product is life.



Questions?



Our business is science. Our product is life.



## Web Sites

Centerwatch.com

Ama-assn.org