SR&ED Practitioner Meeting
Medical Professional Corps (MPC's)
Mar 25, 2021

SREDStakeholder.CA

Presented by

David Sabina, CPA,

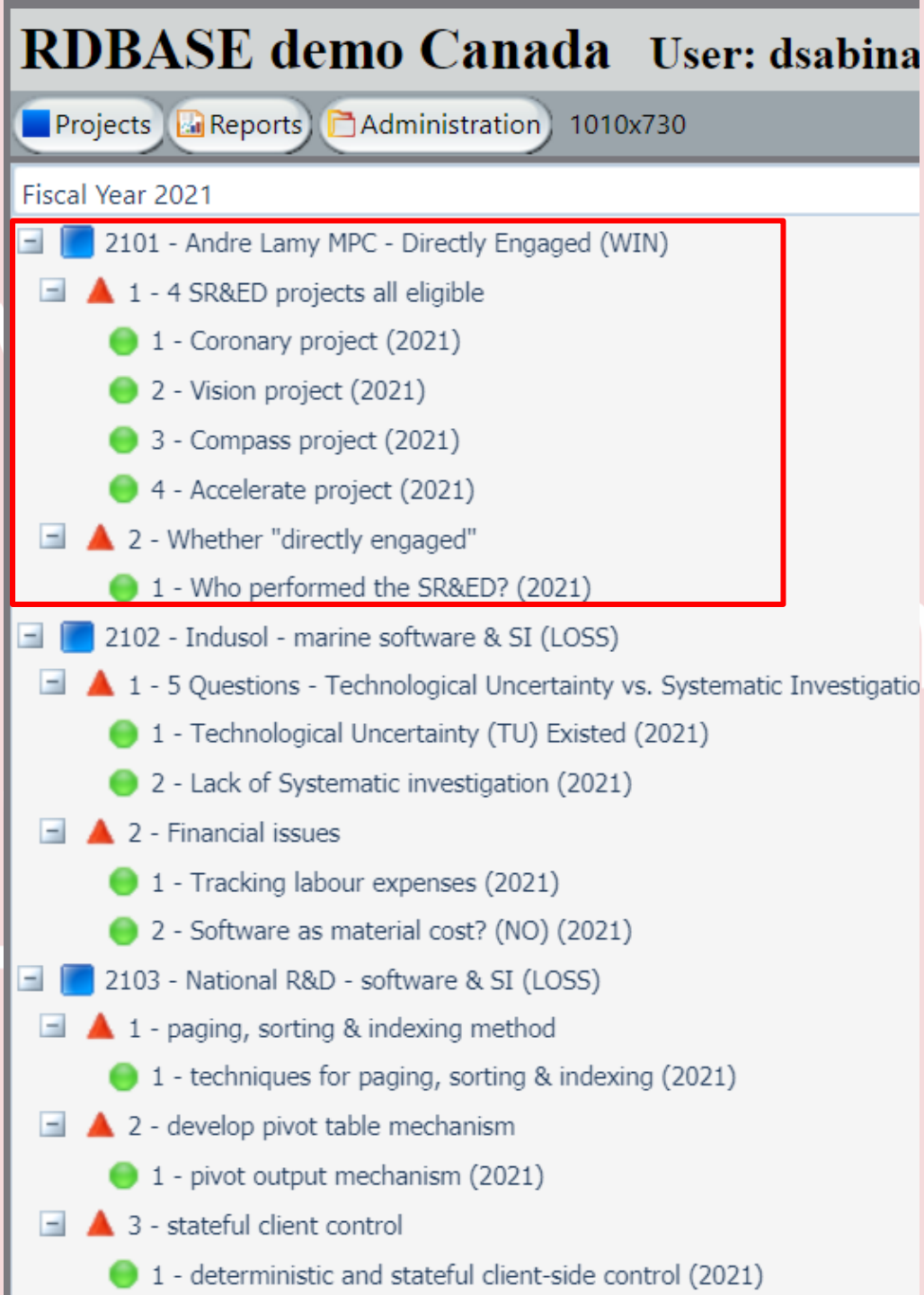
Director, MEUK Corporation

Agenda

- **SR&ED – issues for Medical Professional Corporations (MPC's)**
- presented 2016 - 2020 – partially resolved
  - **1) AFP/APP funding effects – IN PROCESS**
  - **2) Directly Engaged / Undertaken - RESOLVED?**
  - **3) Length of time for objections - RESOLVED**
  - **4) Consistency of rulings across Canada - RESOLVED**
- New issues raised during 2018 & 2019
  - **5) Proving involvement with protocols - ADDRESSED**

SR&ED Medical Issues – in contention with CRA 2016 – 2021

		2021	2020	2019	2017	2016
1	AFP / APP funding as assistance Portion related to SR&ED?	?	PDF Video	PDF Video	PDF Video	PDF Video
2	Directly engaged / entitlement to exploit Doctor vs. MPC?	Dr. Lamy case	PDF Video	PDF Video	PDF Video	PDF Video
3	Contract eligibility tips	CRA 2019 guidance	PDF	PDF Video		
4	Proving input on protocols	Dr. Lamy case	PDF	PDF Video		
5	Speed of appeals (Objections > 4 years +)	Resolved?	PDF	PDF Video		



3 SR&ED cases 2021

"demo" login

WWW.RDBASE.CA

Dr. Lamy MPC Case analyzed using

"key criteria"

&

"project description"

reports.

Review then apply to Medical issues

The RDBASE project

OBJECTIVES > STANDARD PRACTICE	IDENTIFY
STATE of EXISTING KNOWLEDGE	BENCHMARKING SOURCES
OBJECTIVES	BENCHMARKS VS. OBJECTIVES

UNCERTAINTIES & HYPOTHESES	VARIABLES for EXPERIMENTATION

EXPERIMENTS	CORRELATE
RESULTS	OBJECTIVES
CONCLUSIONS	VARIABLES

Key Criteria Summary

2101 - Andre Lamy MPC - Directly Engaged (WIN)			
BENCHMARKS	**ACTIVITIES BY YEAR**		
Competitive products or processes: 56 products	2021		
In-house technologies: 5 products / processes	'1-1	'2-1	'3-1
Queries to experts: 12 responses	Coronary project	Compass - effects Rivaroxaban	Who performed the SR&ED?
OBJECTIVES	**RESULTS**		
On pump primary composite outcome CABG: 13 %	13.3		
Off pump primary composite outcome CABG: 13 %	12.1		
On pump repeat coronary revascularization: 0.5 %	0.8		
Off pump repeat coronary revascularization: 0.5 %	1.4		
UNCERTAINTIES & KEY VARIABLES	**CONCLUSIONS**		
1 - Coronary project - on vs. off pump factors			
Cerebrovascular disease	Y		
Effect of diabetes	Y		
Euroscore	Y		
Left ventricular function: Grade 1 to 4	Y		
Number of vessels diseased	Y		
2 - Compass project			
factors affecting Rivaroxaban		Y	
3 - Whether "directly engaged"			
No			
Yes			Y
	METHODS		
Analysis	2		
Trials	4752	27000	
Prototypes			
Lines of code			
	COSTS		
Hours	500	180	
Materials $			
Subcontractor $			

Project Name:	Andre Lamy MPC - Directly Engaged (WIN)	**Start Date:**	2021-01-01
Project Number:	2101	**Completion Date:**	2021-04-30

Project Details:

Scientific or Technological Objectives:

Measurement	Current Performance	Objective	Has results?
On pump primary composite outcome CABG (%)	12.5	13	Yes
Off pump primary composite outcome CABG (%)	12	13	Yes
On pump repeat coronary revascularization (%)	1	0.5	Yes
Off pump repeat coronary revascularization (%)	1	0.5	Yes

This project example is based on the Tax Court of Canada judgment for Andre Lamy Medicine Professional Corporation v. The Queen (2020 TCC 61).

STATEMENT OF AGREED FACTS

1, The Appellant was a corporation located in Ontario.

2. The Appellant was incorporated on June 23, 2008.

3. Dr. Lamy was the Director, President and Secretary of the Appellant.

4. The Appellant was the medical professional corporation of Dr. Lamy and carried on the business of performing cardiac surgery, providing associated medical care to patients and researching improvements in cardiac surgical methodology and clinical [outcomes].

5. Dr. Lamy was also employed as a Professor of the Faculty of Health Sciences at McMaster University where his teaching duties included lecturing on research methodology and the inclusion of students in cardiac surgery.

6. During the 2013 and 2014 taxation years, Dr. Lamy was involved in experimental projects relating to advancements in cardiac surgical techniques and treatments.

There were two studies known as

the Vision study, that included projects referred to throughout as "Vision" and "Coronary", and

the Compass study, that included projects referred to throughout as "Compass" and "Accelerate" (the “Projects").

[NOTE: CRA CONCEDED ELIGIBILITY OF VISION AND ACCELERATE PROJECTS]

8. Careful SRED time tracking dockets were kept as required, and detailed representations and information packages regarding the Projects were prepared.

9. SRED tax credits for its 2013 and 2014 taxation years in the amounts of $93,828.00 and $107,642.00, respectivelY.

10. The Research Agreements leading to the Projects were signed by Dr. Lamy without noting his capacity as director of the Appellant.

ll. Dr. Lamy was not required by his employment agreement with McMaster University to undertake research within the meaning of subsection 248(1) of the Act.

21. During the 2013 and 2014 taxation years, Dr. Lamy spent approximately 52 to 57 per cent of his time working on these four projects. He testified that he conducted all of his research as an employee of the Appellant.

The largest project (Coronary) involved developing and comparing techniques for Coronary Artery Bypass Grafting (CABG) with or without a pump. WE WILL USE THE FACTS OF THIS PROJECT FOR THIS EXAMPLE.

PROJECT PROTOCOLS:
In a recent survey of Canadian heart surgeons, Desai et al reported that a majority of surgeons believe that off-pump CABG improves clinical outcomes but concerns regarding incomplete revascularization, technical demands and the lack of proven clinical benefits have limited the routine performance of off-pump CABG in Canada.

Many investigators have indicated an urgent need for a large scale RCT of off-pump CABG vs. on-pump CABG with a long-term follow-up. A recent Scientific Statement from the American Heart Association and recommendations from the National Heart, Lung, and Blood Institute Working Group have reiterated the need for a,

“large, multicenter, randomized clinical trial to compare the procedures and the effect of CABG on neurocognition, renal failure, infection, and blood requirements, as well as to explore other questions”.

1.1 Study Objectives

Primary: In patients undergoing CABG surgery, does off-pump CABG surgery compared to on-pump CABG surgery reduce major clinical vascular events in the short term (30 days) and are the benefits maintained at long term (5 years)? The primary outcome at 30 days is total mortality, stroke, MI and new renal failure requiring dialysis and at 5 years, the same outcomes plus repeat revascularization.

We are therefore proposing a large multicentre international randomized trial with long term follow-up to provide definite answers to a clinically important question.We have two co-primary outcomes:

The first co-primary outcome is the occurrence of the composite of total mortality, stroke, nonfatal MI, or new renal failure at 30 days post randomization (randomization = day 1).

The second co-primary outcome is the occurrence of the composite of total mortality, stroke, nonfatal MI, new renal failure, or repeat coronary revascularization (i.e. coronary artery bypass surgery or percutaneous coronary intervention) over 5 years after randomization.

Secondary: In patients undergoing CABG surgery, does off-pump CABG surgery compared to on-pump CABG surgery reduce costs in the short term (30 days) and at long term (5 years) (cost-effectiveness analysis)?

Field of Science/Technology:

Cardiac and cardiovascular systems (3.02.04)

Project Details:

Intended Results:	Develop new processes
Work locations:	Research Facility
Key Employees:	Andre Lamy (Cariothoracic surgery - MD,PhD (2000) / Surgeon)
Evidence types:	Design of experiments; Records of trial runs; Progress reports, minutes of project meetings; Test protocols, test data, analysis of test results, conclusions; Records of resources allocated to the project, time sheets; Samples, prototypes, scrap or other artefacts; Project records, laboratory notebooks; Project planning documents

Scientific or Technological Advancement:

Uncertainty #1: Coronary project - on vs. off pump factors

All of the projects themselves were deemed eligible from a technology perspective.

The CRA's challenges instead related to the issues of whether Dr. Lamy was;

1) performing SR&ED in role as Principal Investigator on projects sponsored by other companies &

2) "directly" vs. "indirectly" engaged on each project.

The following is a brief summary of the uncertainties related to the largest project (Coronary) reproduced from the actual protocols as published:

For the second co-primary outcome at 5 years, it is more difficult to predict if the treatment effect will follow a proportional hazard model or not (an earlier benefit from off-pump CABG could be lost at long term with an excess in re-revascularization per example).

If the proportional hazards assumption holds for outcomes at 5 years, we will proceed as described with the first co-primary outcome above. If the proportional hazards assumption does not hold for outcomes at 5 years, we will fit a Cox model with an extra time-dependent covariate, which is the interaction term between the treatment and the survival time. This time-varying treatment effect will also be examined by the Aalen's additive hazards model.

This type of model will allow the risk to be estimated within discrete time periods to further describe the difference due to treatment group. Participants who prematurely discontinue follow-up before a major cardiovascular event will be censored as to their last follow-up data.

In secondary analyses we will compare the incidence of each of the individual major cardiovascular events (total mortality, stroke, nonfatal MI, new renal dialysis) and revascularization procedures (i.e. coronary artery bypass surgery and percutaneous coronary intervention) using the same strategy.

We will be testing hypotheses for two co-primary outcomes which are correlated with each other. An adjustment to the a level for each of the two tests of the co-primary outcomes is needed. The a level for the test of the first co-primary outcome (0.048) was determined through 10,000,000 simulations while fixing the a level for the test of the second co-primary outcome at 0.01.

APPENDIX A
Protocol Subgroups
-Diabetes
-Cerebrovascular disease
-Peripheral arterial disease
-Left ventricular function: Grade 1 to 4
-Number of vessels diseased: left main, single, double, or triple
-Gender:M/F
-Age: <70 years old, =70 years old
-Euroscore: into 3 groups i.e. 0 to 2, 3 to 5 & >5

The most significant underlying key variables are:

Effect of diabetes, Cerebrovascular disease, Left ventricular function: Grade 1 to 4, Number of vessels diseased, Euroscore

Technology or Knowledge Base Level:

Benchmarking methods & sources for citings:

Benchmark Method/Source	Measurement	Explanatory notes
Competitive products or processes	56 products	https://www.nejm.org/doi/suppl/10.1056/NEJMoa1301228/suppl_file/nejmoa1301228_protocol.pdf These protocols cite 56 other studies relating to variables in the design of the study.
Similar prior in-house technologies	5 products / processes	Dr. Lamy has published peer reviewed papers regarding the states of Coronary project technology. Original invesitagations began 2007.
Queries to experts	12 responses	12 other specialists listed in protocol development

Activity #1-1: Coronary project (Fiscal Year 2021)

Methods of experimentation:

Method	Experimentation Performed
Analysis / simulation:	2 alternatives
Trials:	4752 runs / samples

Improve Coronary Artery Bypass Grafting techniques:

[17] With respect to the Coronary Project, he testified that it related to bypass surgery. He referred to two techniques that are used when conducting bypass surgery.

One is called a cardiopulmonary bypass, or the pump. This involves stopping the heart while the bypass is performed.

The second technique is called off-pump. A pump is not used and the bypass is performed while the heart is beating.

Dr. Lamy noted that there was much discussion in the medical community with respect to which technique is better. As a result, he decided that he would try to answer that question by starting the Coronary Project.

He has been working on the project for ten years and it is not yet completed. He worked on this project during the 2013 and 2014 taxation years.

ADDITIONAL DETAILS FROM INTERNET: PUBLISHED REPORT 2013

Background: Previously, we reported that there was no significant difference at 30 days in the rate of a primary composite outcome of death, myocardial infarction, stroke, or new renal failure requiring dialysis between patients who underwent coronary-artery bypass grafting (CABG) performed with a beating-heart technique (off-pump) and those who underwent CABG performed with cardiopulmonary bypass (on-pump).

Results:

- On pump primary composite outcome CABG: 13.3 % (160% of goal)
- Off pump primary composite outcome CABG: 12.1 % (10% of goal)
- On pump repeat coronary revascularization: 0.8 % (40% of goal)
- Off pump repeat coronary revascularization: 1.4 % (no improvement)

ADDITIONAL DETAILS FROM INTERNET:

Dr. Lamy's most significant contribution in cardiac surgery is the CORONARY trial for which he received a large grant from the Canadian Institute of Health Research in 2007.

CORONARY is a large multi centred randomized trial of off-pump CABG surgery versus on-pump CABG surgery. CORONARY has recruited and randomized 4,752 patients from 79 centres in 19 countries.

The results were presented at the Late Breaking Clinical Trials at the American College of Cardiology meeting in 2012 and 2013 and were published in the New England Journal of Medicine in 2012 and 2013.

The trial recently finished with a follow-up of five years. These final results were published in the New England Journal of Medicine October 2016.

ADDITIONAL DETAILS FROM INTERNET: PUBLISHED REPORT 2013

Results: At 1 year, there was no significant difference in the rate of the primary composite outcome between off-pump and on-pump CABG (12.1% and 13.3%, respectively; hazard ratio with off-pump CABG, 0.91; 95% confidence interval [CI], 0.77 to 1.07; P=0.24).

The rate of the primary outcome was also similar in the two groups in the period between 31 days and 1 year (hazard ratio, 0.79; 95% CI, 0.55 to 1.13; P=0.19).

The rate of repeat coronary revascularization at 1 year was 1.4% in the off-pump group and 0.8% in the on-pump group (hazard ratio, 1.66; 95% CI, 0.95 to 2.89; P=0.07).

There were no significant differences between the two groups at 1 year in measures of quality of life or neurocognitive function.

Conclusion:

[47] [the CRA conceded eligibility of the] Vision and Accelerate Projects.

However, the Respondent (CRA) argues that the documents provided with respect to the Coronary Project and the Compass Project are not consistent with a factual finding that the Appellant performed the SR&ED.

I (the judge) do not agree.

CONCLUSIONS - DETAILS FROM INTERNET: PUBLISHED REPORTS 2013 & 2016

Conclusions: At 1 year after CABG, there was no significant difference between off-pump and onpump CABG with respect to the primary composite outcome, the rate of repeat coronary revascularization, quality of life, or neurocognitive function.

In our trial, the rate of the composite outcome of death, stroke, myocardial infarction, renal failure, or repeat revascularization at 5 years of follow-up was similar among patients who underwent off-pump CABG and those who underwent on-pump CABG.

AUTHOR'S NOTE:

BECAUSE THE PROJECT WAS SPONSORED BY ANOTHER PARTY (CANADIAN INSTITUTE FOR HEALTH RESEARCH) THE CRA SCRUTINIZED WHETHER THE SPONSOR OR DR. LAMY WAS CONDUCTING THE SR&ED. IN THIS CASE HE APPEARED TO HAVE BEEN THE PRIMARY DESIGNER OF THE PROTOCOLS.

Significant variables addressed: Cerebrovascular disease, Effect of diabetes, Euroscore, Left ventricular function: Grade 1 to 4, Number of vessels diseased

Documentation:

- Uploaded to RDBASE.NET: Dr. Andre Lamy Published reports on Coronary Project.pdf (153KB), Andre Lamy MPC SRED Tax ruling -WIN Directly Engaged.pdf (202KB), Effects of off-pump and on-pump coronary-artery bypass grafting at 1 year - PubMed.pdf (85.2KB)
- Offline Documents: docs

Uncertainty #2: Compass project

The most significant underlying key variables are:

factors affecting Rivaroxaban

Technology or Knowledge Base Level:

Activity #2-1: Compass - effects Rivaroxaban on cardiac patients (Fiscal Year 2021)

Methods of experimentation:

Method	Experimentation Performed
Trials:	27000 runs / samples

[19] The Compass Project is a large trial project. Dr. Lamy was involved in a small portion of the project; that portion involved testing the medication Rivaroxaban with certain patients.

Dr. Lamy noted this his involvement related to the small portion of the test population who had undergone cardiac surgery. He worked on the project during the 2013 and 2014 taxation years and continues to work on the project today.

[28]Compass Project (the “Compass Letter of Understanding”). The letter is signed by the Hamilton Health Sciences Corporation (identified in the letter as “HHSC”) and Dr. Lamy.

The purpose of the Compass Letter of Understanding appears to be to discuss HHSC’s and Dr. Lamy’s role in the Compass Project, which was sponsored and funded by Bayer Healthcare AG. Dr. Lamy noted that worldwide there were approximately 27,000 patients who participated in the Compass Project.

[29] The letter states that Bayer Healthcare AG has authorized Bayer Inc., a corporation with an address in Toronto, to act on its behalf regarding all matters related to the conduct of the study in Canada.

[30] The Compass Letter of Understanding indicates that Bayer Inc. has entered into a clinical trial service agreement with HHSC, pursuant to which HHSC is to manage the Compass Project, including supervising the investigators.

The letter refers to Dr. Lamy as being the “Principal Investigator.” In his testimony, Dr. Lamy clarified that there were approximately 600 investigators involved in the Compass Project and that he was the local Principal Investigator, meaning he was the Principal Investigator for the patients in the Hamilton hospital.

[31] It appears that the role of the Principal Investigator was to pre-screen patients and then recruit qualifying patients for the project.

Appendix A states that the Principal Investigator shall carry out the “Study Activity”. The Compass Letter of Understanding does not explain this term. It appears to relate to activities HHSC was required to perform under its agreement with Bayer Inc. I was not provided with a copy of that agreement.

[AUTHOR'S NOTE: THIS TYPE OF INFORMATION WILL BE RELEVANT IN HELPING THE JUDGE ASSESS DR. LAMY'S INVOLVEMENT IN THE PROTOCOL DESIGN. GIVEN THE SUCCESSFUL RESULT WE WILL ASSUME IT IS SIMILAR TO THE CORONARY PROJECT.]

[32] On the second page of the Compass Letter of Understanding it is stated that HHSC, on behalf of Bayer Inc., shall pay Dr. Lamy for the services provided in accordance with Appendix B to the letter of understanding.

Dr. Lamy testified that HHSC did not pay any amounts to either him or the Appellant in respect of the Compass Project. The only monies he received were the amounts paid to him by the Appellant as salary.

[AUTHOR'S NOTE: PAYMENTS FOR THE RESEARCH FROM ANOTHER CANADIAN COMPANY MAY BE "CONTRACT PAYMENTS" TO REDUCE ELIGIBLE SR&ED.]

Results:

THE CASE DID NOT PROVIDE SPECIFIC DETAILS ON THIS PROJECT. SINCE IT WAS SPONSORED BY A PRIVATE COMPANY (BAYER) THE RESULTS ARE NOT PUBLIC.

Conclusion:

[47] [the CRA conceded eligibility of the] Vision and Accelerate Projects.

However, the Respondent (CRA) argues that the documents provided with respect to the Coronary Project and the Compass Project are not consistent with a factual finding that the Appellant performed the SR&ED.

I (the judge) do not agree.

[AUTHOR'S NOTE: BECAUSE THE PROJECT WAS SPONSORED BY ANOTHER PARTY (I.E. BAYER PHARMACEUTICAL COMPANY / RIVAROBAXIN PRODUCER) THE CRA SCRUTINIZED WHETHER THE SPONSOR OR DR. LAMY WAS CONDUCTING THE SR&ED.

IN SUCH CASES IT IS IMPORTANT TO OUTLINE HOW;

- THE PERFORMER (DR. LAMY) PROVIDED INPUT INTO THE PROTOCOL DESIGN ITSELF VS.
- JUST PROVIDING DATA FOR THE SPONSOR TO INTERPRET & ANALYZE.]

Significant variables addressed: factors affecting Rivaroxaban

Uncertainty #3: Whether "directly engaged"

The most significant underlying key variables are:

Yes, No (unresolved)

Technology or Knowledge Base Level:

Activity #3-1: Who performed the SR&ED? (Fiscal Year 2021)

Methods of experimentation:

The court examined contracts related to 2 of the projects.

[34] Dr. Lamy testified that he signed the Coronary Agreement and the Compass Letter of Understanding in his capacity as an employee of the Appellant, since he provided the services specified in the agreement and the Compass Letter of Understanding as an employee of the Appellant.

[36] As I noted previously, the issue before the Court is whether the Appellant carried out the SR&ED or whether Dr. Lamy conducted such research in his personal capacity. This is a question of fact.

[37] The Respondent (CRA) presented no witnesses in support of her factual conclusion that Dr. Lamy carried out the SR&ED

in his personal capacity.

The only subparagraphs that support the Minister's argument that Dr. Lamy, and not the Appellant, conducted the SR&ED are subparagraphs 10 e) and f) of the Reply. These subparagraphs contain the following factual conclusions:

e) the SR&ED in question was undertaken by Dr. Lamy in his personal capacity; and

f) the SR&ED in question was not undertaken directly by the Appellant nor on behalf of the Appellant by Dr. Lamy.

[38] The Reply does not contain any assumptions of fact made by the Minister that support these two factual conclusions.

As a result, I will base my decision on the relevant evidence before me, namely, the testimony of Dr. Lamy, the admissions made by the parties, the facts contained in the SAF and three of the documents included in Exhibit AR-1.

[52] That it was Dr. Lamy who signed the Coronary Agreement and the Compass Letter of Understanding does not change the fact that he performed the research activities as an employee of the Appellant.

Dr. Lamy acknowledged that he signed the Coronary Agreement and the Compass Letter of Understanding as Andre Lamy. He noted that this is how he signs all documents.

However, he stated that he signed the documents in his capacity as an employee of the Appellant, since he provided the services as an employee of the Appellant.

[53] Dr. Lamy's testimony is supported by the billings made for his medical services.

He bills the Government of Ontario for such services in his own name.

The Respondent does not challenge the Appellant's position that any monies received in respect of such services are received by Dr. Lamy for and on behalf of the person providing the service, i.e., his employer, the Appellant.

The result is the same with respect to the research activities: Dr. Lamy signed his own name on the contracts, but he provided the services as an employee of the Appellant. [CONSISTENCY]

Results:

[39] As I noted previously, Dr. Lamy testified that he performed all of his research activities as an employee of the Appellant. His testimony is consistent with the admissions made by the Respondent and the subjective evidence before me.

[43] Since Dr. Lamy is the only employee of the Appellant, clearly he is the only one conducting the business of the Appellant, namely performing surgery, providing care to patients and conducting medical research. In other words, if the Appellant carried out the research in question in these appeals, then Dr. Lamy had to perform the research work.

[54] The evidence before me is that from 2008 until the present time any activities of Dr. Lamy relating to the business of the Appellant, including researching improvements in cardiac surgery, were activities of his employer, the Appellant.

[44] The Employment Agreement specifically provides that Dr. Lamy shall not devote any of his time to any business other than the business of the Appellant. He testified that he complied with this provision and I received no evidence to contradict his testimony.

Conclusion:

[46] On the basis of these facts and the other evidence before me, I conclude that the Appellant performed the SR&ED.

Dr. Lamy physically performed his research as an employee of the Appellant.

[AUTHOR'S NOTE: THIS PROVIDES A DEGREE OF CLARITY TO ALL CLAIMS BY MEDICAL PROFESSIONAL CORPORATIONS. SPECIFICALLY IT RECOGNIZES THAT THE DOCTOR HIM OR HERSELF CAN REPRESENT THE CORPORATION WHEN SIGNING DOCUMENTS.]

Significant variables addressed: Yes

FEATURED PUBLICATIONS

Let's review Excerpts from published protocols

- Lamy A, Devereaux PJ, Prabhakaran D, Taggart DP, Hu S, Straka Z, Piegas LS, Avezum A, Akar AR, Lanas Zanetti F, Jain AR, Noiseux N, Padmanabhan C, Bahamondes JC, Novick RJ, Tao L, Olavegogeascoechea PA, Airan B, Sulling TA, Whitlock RP, Ou Y, Gao P, Pettit S, Yusuf S, CORONARY Investigators. Five-Year Outcomes after Off-Pump or On-Pump Coronary Artery Bypass Grafting. N Engl J Med. 2016 Oct 23 doi:10.1056/nejmOA1601564.

- Lamy A, Tong W, Devereaux PJ, Gao P, Gafni A, Singh K, Taggart D, Straka Z, Akar AR, Piegas L, Ou Y, Yusuf S. The Cost Implications of Off-Pump Versus On-Pump Coronary Artery Bypass Graft Surgery at One Year. Ann Thorac Surg:2014 Nov;98(5):1620- 5 PMID:25261272.

- Lamy A, Devereaux PJ, Prabhakaran D, Taggart D, Hu S, Paolasso E, Straka Z, Piegas L, Akar A, Jain A, Noiseux N, Padmanabhan C, Bahamondes J, Novick R, Vaijyanath P, Reddy S, Tao L, Olavegogeascoechea P, Airan B, Sulling TA, Whitlock R, Ou Y, Ng J, Chrolavicius S, Yusuf S, The CORONARY Investigators Off-Pump or On-Pump Coronary-Artery Bypass Grafting at 30 Days. N. Eng Med. 2012 Apr 19;366(16):1489-97.

- Lamy A, Devereaux PJ, Prabhakaran D, Hu S, Piegas LS, Straka Z, Paolasso E, Taggart D, Lanas F, Akar AR, Jain A, Noiseux N, Ou Y, Chrolavicius S, Ng J, Yusuf S. Rationale and design of the Coronary Artery Bypass Grafting Surgery Off or On Pump Revascularization Study: A large international randomized controlled trial in cardiac surgery. Am Heart J. 2012 Jan; 163 (1) 1-6.

Coronary Protocols developed by Dr. Lamy

Table of Contents

Project started by citing other studies

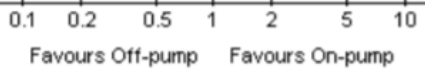
LAMY, Andre
Project Title: CABG Off or On Pump Revascularization Study (CORONARY)

Table 1 Meta-analysis of RCTs (graft patency)

Review: Off-pump Patency_4 studies
Comparison: 01 Off-pump CABG versus On-pump CABG
Outcome: 01 Patency (inverse)

Study or sub-category	On-pump n/N	Off-pump n/N	RR (fixed) 95% CI	RR (fixed) 95% CI	Order
Khan	127/130	114/130		1.11 [1.04, 1.19]	1
Lingaas	153/163	124/140		1.06 [0.99, 1.14]	2
Puskas	249/260	235/251		1.02 [0.98, 1.07]	3
Nathoe	83/89	63/69		1.02 [0.93, 1.12]	4
Total (95% CI)	642	590		1.05 [1.02, 1.08]	

Total events: 612 (On-pump), 536 (Off-pump)
Test for heterogeneity: Chi² = 4.75, df = 3 (P = 0.19), I² = 36.8%
Test for overall effect: Z = 3.12 (P = 0.002)



Results correlated to causes

Table 2. Results of the Canadian off-pump CABG Registry (modified from Lamy et al [25])

Propensity score-matched in-hospital and one-year outcomes

	Off-pump (n=1,233)	On-pump (n=1,233)	Odds ratios (95% CI)	P value
In-hospital				
Mortality (%)	1.5	1.7	0.90 (0.48, 1.69)	0.750
Stroke (%)	0.8	1.6	0.49 (0.23, 1.06)	0.072
Myocardial infarction (%)	3.0	1.5	2.09 (1.18, 3.69)	0.011
Acute renal disease*	0.4	1.4	0.23 (0.08, 0.69)	0.009
Graft completed (mean +/- SD)	2.62 +/- 1.0	3.36 +/- 0.9		p<0.01
One-year†				
Mortality (%)	3.5	3.9	0.90 (0.59, 1.38)	0.643
Stroke (%)	1.4	2.7	0.49 (0.27, 0.90)	0.021
Myocardial infarction (%)	3.9	3.0	1.32 (0.85, 2.06)	0.215
Renal dialysis* (%)	1.1	2.1	0.51 (0.25, 1.02)	0.058
Coronary angiogram (%)	3.3	3.8	0.86 (0.55, 1.33)	0.502
Coronary revascularization (%)	1.9	1.9	1.02 (0.56, 1.86)	0.936

*Patients on renal dialysis at baseline were excluded from analysis

Analysis 30 days post operation New Variables

LAMY, Andre
Project Title: CABG Off or On Pump Revascularization Study (CORONARY)

Table 3. Results of a meta-analysis (modified from Cheng et al [27])

In-hospital or 30 days outcomes [number of patients at risk]	Off-pump	On-pump	Odds ratios (95% CI)	P value
Mortality (%) [3082 patients]	1.2	1.0	1.02 (0.58, 1.80)	0.9
Stroke (%) [2859]	0.4	1.0	0.68 (0.33, 1.40)	0.3
Myocardial infarction (%) [2721]	2.0	2.8	0.77 (0.48, 1.26)	0.2
Acute renal failure [1467]	0.9	2.1	0.58 (0.25, 1.33)	0.2
Neurocognitive dysfunction [335]	40.0	50.6	0.57 (0.21-1.54)	0.5
Atrial fibrillation [2425]	17.6	26.8	0.58 (0.44-0.77)	<0.001
Transfusions [2412]	28.4	42.5	0.43 (0.29-0.65)	<0.001
Re-exploration for bleeding [2307]	1.7	2.2	0.81 (0.44-1.49)	0.5
Inotropes use [1655]	15.1	23.6	0.48 (0.32-0.73)	<0.001
Intra aortic balloon pump [1262]	1.1	1.0	1.07 (0.39-2.89)	0.9
Mediastinitis/wound infection [2076]	3.0	4.8	0.65 (0.41-1.04)	0.07
Respiratory infection [896]	4.6	9.9	0.41 (0.23-0.74)	<0.001
Number of grafts	2.6	2.8		<0.001

5.3 Visit Schedule

Table 4: Schedule of follow-up.

VISIT SCHEDULE	Pre-op	OR Day	Day 1	Day 2	Discharge	30 Day	6 Mth*	Yr 1	Yrs 2-4*	Final Visit
Inclusion/Exclusion Criteria	✓									
Informed Consent	✓									
Patient Demography	✓									
Baseline Blood & ECG	✓									
Medical History	✓				✓					
Details of Surgical Procedure		✓								
Patient Evaluation	✓									
Outcomes Events					✓	✓	✓	✓	✓	✓
CKMB	✓		✓	✓						
Creatinine	✓				✓			✓		✓
ECG	✓					✓				✓
MoCA, Trail Making Test, DSST and EuroQoL	✓				✓	✓		✓		✓

Sample size and scope of work

Table 5a: Sample size to detect RRR in the ranges of 25 to 35% at various event rates for first co-primary outcome at 30 days (no loss to follow-up, conversion rate from on-pump to off-pump is assumed at 1% and from off-pump to on-pump is at 2.7%). We are proposing a sample size of 4,700 patients.

On-Pump Event Rate	Hazard Ratio	Power		
		80%	85%	90%
0.08	0.65	2861	3271	3825
	0.70	4016	**4591**	5368
	0.75	5958	6810	7964
0.09	0.65	2541	2904	3396
	0.70	3566	4077	**4767**
	0.75	5292	6049	7074
0.10	0.65	2284	2611	3053
	0.70	3207	3665	4286

Mortality Shift vs. Tables 2 & 3
Higher Earlier but Lower > 1 year

Table 5b: Expected results of the CORONARY study

	Off-pump	On-pump	Relative risk
30 days			
Mortality (%)	2.1	2.1	1.0
Stroke (%)	0.97	1.9	0.51
Myocardial infarction (%)	3.95	5.0	0.79
Acute renal failure	0.75	1.8	0.42
Composite Outcome (all events)	7.77	10.8	0.72
Composite Outcome (first event)	6.37	8.86	0.72
One-year			
Mortality (%)	2.8	3.0	0.93
Stroke (%)	1.6	3.3	0.48
Myocardial infarction (%)	5.4	6.4	0.84
Acute renal failure (%)	1.3	2.5	0.52
Coronary revascularization (%)	2.5	1.9	1.3
Composite Outcome (all events)	13.6	17.1	0.80
Composite Outcome (first event)	10.2	12.8	0.80
Composite Outcome (first event) 5 years	17.6	22.0	0.80

Table 7: Direct costs (adapted from Cheng et al [27])

Study	Difference during the Initial Hospitalization*	Difference at 1 year *	P value
Ascione[55]	USD $1,117	N/A	p<0.001
Lee[56]	USD $5,273	N/A	p<0.0001
Nathoe [14]	USD $1,375	USD $1,839	p<0.001
Straka[26]	Euro € 936	N/A	p<0.001
Puskas [13]	USD $2,272	USD $1,955	p<0.0001
Lamy [25]**	CAN $2,020	CAN $2,112	p<0.001

* All studies demonstrate lower costs in off-pump CABG compared to on-pump CABG
** Non-randomized study
N/A Not Available

Table 2: Propensity Score Pair-Matched Costs Comparisons from the Canadian Off-pump CABG Registry[10]

	Off-pump N=1,233	On-pump N=1,233	P value
Initial Hospitalization Costs	$11,744 ± $237	$13,720 ± $301	0.001
CABG Procedure	$5,013	$5,147	n.s.
Surgical Device	$264 ± $8.8	$790	0.001
Post-op ICU	$3,422 ± $187	$4,106 ± $244	0.026
Post-op Ward	$3,045 ± $98	$3,676 ± $150	0.001
Total Blood Products	$28 ± $3.9	$79 ± $3.9	< 0.001
Follow-Up Costs	$319 ± $54	$421 ± $65	0.016
One-Year Accumulative Costs	$12,063 ± $243	$14,141 ± $307	0.001

* All costs expressed in mean ± sem based on non-transformed dataset.

Description and Rationale of Protocol Modifications

Original	Not applicable
Revision	Section 8 Substudies and Ancillary Studies **<u>Renal Substudy</u>** **Acute kidney injury (AKI) is an abrupt loss of kidney function and occurs frequently in people who are ill (~ 15% of cardiac surgeries, 5% of hospital admissions, and up to 50% of patients in the intensive care unit). AKI is recognized by observing a sudden rise in serum creatinine. This rise in serum creatinine is invariably modest and transient, with the value returning back to a level which predated the AKI. Historically AKI by this definition was believed to have no lasting impact. More recently a growing number of clinical studies highlight the association between AKI and the subsequent development of a permanent reduction in kidney function termed chronic kidney disease (CKD, includes the need for permanent long-term dialysis). This association is also supported by animal studies where the AKI event altered the renal microvasculature with subsequent upregulation of inflammatory and fibrotic signaling pathways. However, it remains unknown whether avoiding AKI prevents CKD.** **Compared to on-pump CABG, it is strongly expected that off-pump CABG will prevent AKI (73% relative risk reduction was observed in meta-analysis). The data currently collected in CORONARY will be augmented to include serum creatinine measurements in the perioperative period, one year and five year/final follow-up period for study patients. By doing so, it will determined if performing CABG surgery without bypass results in less CKD, and whether this association is mediated by the avoidance of transient elevations in serum creatinine (AKI).**

SR&ED Medical Issues – in contention with CRA 2016 – 2021

		2021	2020	2019	2017	2016
1	AFP / APP funding as assistance Portion related to SR&ED?	?	PDF Video	PDF Video	PDF Video	PDF Video
2	Directly engaged / entitlement to exploit Doctor vs. MPC?	Dr. Lamy case	PDF Video	PDF Video	PDF Video	PDF Video
3	Contract eligibility tips	CRA 2019 guidance	PDF	PDF Video		
4	Proving input on protocols	Dr. Lamy case	PDF	PDF Video		
5	Speed of appeals (Objections > 4 years +)	Resolved?	PDF	PDF Video		

Issue 1 -"All AFP or surgical funding SR&ED assistance"

CRA stated,

- "The doctor being a member of the Department of the hospital AFP Practice Plan is receiving **$X of AFP academic funding** from the Government of Ontario, as well as receiving **$Y of surgical repair funding**.
- These amounts … considered Government Assistance … per subsection 127(18) of the ITA."

Update to position 2020

AFP agreement defined

- "Academic funds" as "monies to support teaching and research activities by Participating Physicians" and
- "Clinical Repair Funds" as "monies to support clinical activities by Participating Physicians".
- Therefore, we conclude that part of the academic funding was in respect of the SR&ED. Since **Y% of Dr. X's' time is dedicated to research per the "Letter of Offer"** provided, we are reducing the qualified expenditures by Y% of the academic funding received.

Our comment on 2020/21 position

- New CRA allocations either $0 or attempting a reasonable basis vs. 100% prior
- CRA did not appear to propose any AFP payments to Dr. Lamy SR&ED related
- All positive steps by CRA

Guidelines from SR&ED Director General – May 2, 2019

- Government assistance – whether AFP or any other funding included?

This item is still under review by Rulings/Legal Services. For now, we must continue to apply the contract payment policy.

Legislation

- Income tax act “Reduction of qualified expenditures” (127(18))
  - “Where …taxpayer has received, is entitled to receive or can reasonably be expected to receive a particular amount that is government assistance, non-government assistance or a contract payment that can **reasonably be considered to be in respect of** scientific research and experimental development, …

AFP Practice Models – purpose & variations

Ontario

HealthForceOntario

Specialist Practice Models

Compensation Options

Specialists in Ontario may be compensated through a fee for service system or through an Alternative Funding Plan (AFP) or Alternative Payment Plan (APP). AFPs/APPs are contractual arrangements between the Ministry of Health and Long-Term Care and a group of physicians, and may include other organizations such as hospitals and universities. Some AFPs/APPs also include funding for teaching and research.

These agreements provide flexibility in practice, encourage coordination and integration of medical services, and stabilize compensation for highly specialized groups, specialists and sub-specialists. AFPs/APPs have become more attractive and desirable to many physicians seeking a more balanced working life, regular hours, and acknowledgement of patient acuity, geographical challenges and financial security.

Over the years, a variety of compensation models have been developed and used by AFPs/APPs. Presently, most agreements are blended models that combine a base rate, incentive/premium payments and possibly a fee-for-service component payment. There are several remuneration methods:

- Global/block funding based on specific services or locations
- Blended funding models that include a base payment for clinical services, teaching, research, administration or indirect services plus a premium payments, which could be based on a percentage of the value of Fee-for-Service billings
- Bed utilization rate
- Sessional payment plus fee-for-service billings

AFP/APP Models

There are a variety of models used to cover:

- Specific communities and under-serviced specialties
- Individual departments in a single hospital
- Entire services of all physicians at a single hospital
- Services of all full-time specialists at an academic health science centre
- Province-wide gynaecology oncology, radiation oncology and medical oncology services
- Emergency services in hospitals, specialist services in the north and agreements with specialists and subspecialists associated with academic health science centres
- Regional trauma hospitals to ensure the 24-hour availability of high-level care for patients with serious trauma (Trauma Team Leader global funding agreements)
- Academic Health Science Centres, for clinical services, education and research
- Services such as psychiatry, the Regional Surgical Network, neurosurgery/neurology and anaesthesia in northern regions

For more information, read the Ministry's Resource Manual for Physicians.

Author's summary / opinions

1) Need for disclosure of SR&ED portion

- Many uses of funds,
  - Many require breakdown of research / AFP approved by every member however,
  - procedure seldom followed.
- Nature of AFP model
  - strong argument that none, or perhaps only a minimal amount AFP funding
  - directly related to SR&ED
  - More REGULATION than ASSISTANCE
  - **Recent CRA approaches "reasonable" allocation**

Author's summary / opinions

2) Status of current CRA position unclear

Currently not being reduced?

- Since early 2020 CRA seems to have stopped treating full AFP payments as "assistance"

Still need for national direction

- Additional direction& examples would be welcome on issues including
  - Typical ranges or % by specialty if not specified
  - Perhaps supported by discussions with industry

Recommendations

1) Improve reporting by hospitals

- If hospitals / universities begin to
  - report the “research” component
  - of any AFP funding
  - should resolve “assistance” issue

Issue 2 -
CRA Statement :“directly undertaken”

In assessing the claim for wages paid to Dr. X in his MPC the CRA stated,

- “We have determined that the specified wages claimed were not incurred for scientific research and experimental development **"directly undertaken by the taxpayer" nor** was it for work "directly undertaken **on behalf** of the taxpayer" as required under Paragraph 37(1) (a) and Subparagraph 37(1) (a) (i) of the Income Tax Act (ITA).

Issue 2 - “Directly Undertaken”

Dr. Lamy judgement clarifies that

- The individual doctor should be able to act on behalf of the MPC
- Note that Dr. Lamy was only employee of MPC and contract specified no other work allowed

- ISSUE APPEARS TO BE RESOLVED IN CLAIMANTS FAVOUR

3) Objection delays Guidelines from SR&ED Director General – May 2, 2019

- the length of time that objections & appeals are taking to be addressed.

As Appeals is independent of SR&ED, we don't have this information at hand. We are however in discussion with Appeals and they are aware of the direction we are taking.

Status March 2021

Based on discussions with SR&ED practitioners the backlog on these objections appears to have been remove.

As a result we consider this issue RESOLVED.

4) Consistency of Assessments Guidelines from SR&ED Director General – May 2, 2019

- Consistency of the application of these policies across Canada & within regions &/or

The guidance will be shared Nationally and the HQ plans to continue monitoring these claims to help ensure consistency and identify any further guidance or training requirements that may arise. We are also briefing the A/Ds in person shortly on the file.

5) Evidence of protocol design Guidelines from SR&ED Director General – May 2, 2019

- Challenging if the Dr. was involved on protocol designs (e.g. What evidence is relevant)?

Medical guidance document does not specifically address this. It does speak generally to documentation for the work performed and the importance of agreements demonstrating the research relationships and responsibilities.

What if example, claimant provides

- list recommended changes to protocols &
- Supporting emails, transcripts & sponsor support letters confirming inputs & significant resultant protocol changes.

What if CRA responds,
"No documents available to substantiate claimant contribution toward scientific input to hypothesis formulation, study design, and protocol." - **How to prove?**

Implications of Dr. Lamy MPC case

- CRA challenged work on 2 sponsored projects
- Ruling - Dr. Lamy eligible on ALL projects
- Case provides excellent examples of
  - Strong evidence of input on protocols (Coronary Project) government sponsored & open source
  - Less evidence of involvement (Compass project) for Bayer & private
  - **Risk the CRA may challenge input despite strong evidence – e.g. Coronary project challenged**

Documents typically requested

- Evidence of scientific uncertainties
- Departures from routine practice
- Study protocols & amendments
- Research Ethics Board documentation
- Clinical Study agreements
- Consent Form(s)
- Other docs; laboratory notebook entries, data analyses, meeting minutes, emails, etc.

Recommendations

- Document all input on protocol design
- Document R&D time clearly vs. other professional obligations, clinic time, patient time, academics, …
- Include evenings & weekends if appropriate
  - legitimately, many doctors use for private research
- Ask for a PCPR (Pre Claim Project Review)?

FTCAS – don't quit > strike 1

- First Time Claimant Advisory Service
- First time MPC claims often receive a presentation which clearly dissuades against further claims
- The next claim may be approved even after an intimidating FTCAS (first) meeting
- Less of problem >2018 but many may have dissuaded