Performance of the Saskatoon Centre for Patient-Oriented Research over the Three-Year Pilot Period

June 2014

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Introduction

The Saskatoon Centre for Patient-Oriented Research (SCPOR) is a centralized clinical research resource that standardizes clinical and administrative procedures for the conduct of human research. SCPOR (pronounced "skipper") provides investigators at the University of Saskatchewan (U of S), Saskatoon Health Region (SHR) and Saskatchewan Cancer Agency (SCA) with the resources, know-how and facilities needed to conduct clinical research. It does so in a manner that withstands legal scrutiny and follows good clinical practice guidelines.

Building on the former Saskatchewan Drug Research Institute, SCPOR was created in May 2011 as a joint initiative of the U of S, SHR and SCA. The creation of SCPOR allowed the U of S to join its fellow U15 institutions in providing capacity and facilities needed to conduct clinical research. The U of S's Management and Insurance Services was a strong advocate of the creation of SCPOR for the benefits it would provide in mitigating the risk associated with conducting clinical research. The U of S College of Medicine is a primary recipient of SCPOR's services and provides SCPOR with significant financial support.

SCPOR offers clinical research services and facilities that meet high standards for safety, efficacy and regulatory compliance. SCPOR has well-trained and certified personnel who provide the following services to clinical investigators:

- Negotiating contracts and study budgets
- Preparing and submitting ethics applications
- Preparing and submitting applications for health region approval
- Making regulatory submissions to Health Canada
- Providing research-related financial services (paying study-related expenses, invoicing sponsors, processing sponsor payments, etc.)
- Clinical Research Nurse and Clinical Research Coordinator services

SCPOR's facilities include an eight-bed Clinical Research Unit (CRU) at Saskatoon City Hospital, a contribution of the Saskatoon Health Region. The CRU allows investigators to conduct research in highly controlled conditions, with physician supervision and emergency response on-site.

This report describes SCPOR's progress over its three-year pilot period (May 2011-May 2014) and the outlook for SCPOR's immediate future.

Table 1. SCPOR Metrics (Legend: green – met target; red – did not meet target; H1 – first half; H2 – second half)

ID	Indicator	Frequency	Target	Fiscal Year (With % Increase/Decrease)*		
				2011-2012	2012-2013	2013-2014
CLINICAL RESEARCH SUPPORT						
A1	Number of new studies (overall)	Yearly	10% increase	36	48 (31%)	42 (-12%)
A2	Number of new industry-sponsored studies	Yearly	10% increase	26	34 (27%)	30 (-12%)
A3	Number of new investigator-initiated studies	Yearly	10% increase	10	14 (40%)	12 (-14%)
A4	Number of studies using comprehensive SCPOR services (contract review, REB, budgeting, operational approval, financial services)	Yearly	10% increase	151	154 (2%)	160 (4%)
A5	Number of active investigators	Yearly	80% of U of S clinical investigators	51 % not available	53 % not available	55 45% (approx.)
A6	Total revenue generated	Yearly	5% increase	$443,643	$493,490 (11%)	$529,418 (7%)
A7	Percent of target enrollment achieved	Yearly	5% increase	50%	66% (32%)	69% (5%)
A8	Investigator and coordinator satisfaction	Yearly	10% improvement	Not available	Not available	Not available**
CLINICAL RESEARCH UNIT						
B1	Number of hours of room bookings at Clinical Research Unit	Semi-annually	10% semi-annual increase	H1: 0 / H2: 0	H1: 107 / H2: 0 (-100%)	H1: 435 / H2: 82 (-81%)
B2	Patient experience	Yearly	10% improvement	Not available	Not available	Not available
TRAINING						
C1	Number of courses/workshops in clinical trials methodology provided by SCPOR	Yearly	3 per year	3	3	2***
C2	Handbook for Clinical Researchers	3-year pilot	Publish handbook			Published

*The fiscal year runs from May 1 to April 30.

**The initial user satisfaction survey was run in March 2014. A year-to-year comparison will not be available until spring 2015.

***A third workshop was originally scheduled for April 2014 but was postponed until May 2014.

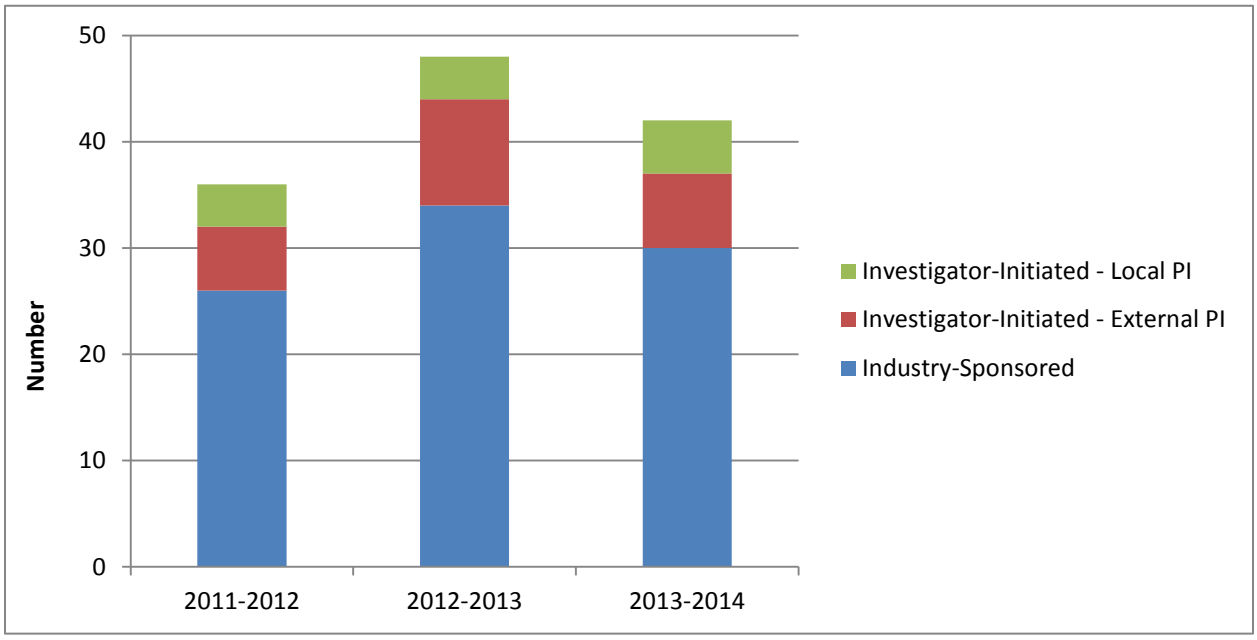
Performance Metrics

In 2013, the SCPOR Members' Executive Committee put in place a set of metrics to evaluate SCPOR's effectiveness and performance. The metrics and their frequencies of measurement, performance targets and results over the three years of the SCPOR pilot period, are listed in Table 1.

New Studies

SCPOR saw a substantial increase in new studies from the first to the second years of the SCPOR pilot but experienced a decline in the third year (Table 1 and Figure 1). In the second year, the number of new studies overall, new industry-sponsored studies and new investigator-initiated studies increased by 31%, 27% and 40%, respectively (Table 1, metrics A1-A3). As a result, for that year SCPOR far exceeded its target of a 10% annual increase for each of these three categories of studies. In the third year, however, there was a decline in the number of new studies in all three categories, resulting in a failure to meet the targeted 10% increase. Over the entire pilot period, there was a net increase in new studies of 17% (from 36 in the first year to 42 in the third year). Among new studies during the pilot, 71-72% were industry-sponsored and 28-29% were investigator-initiated.

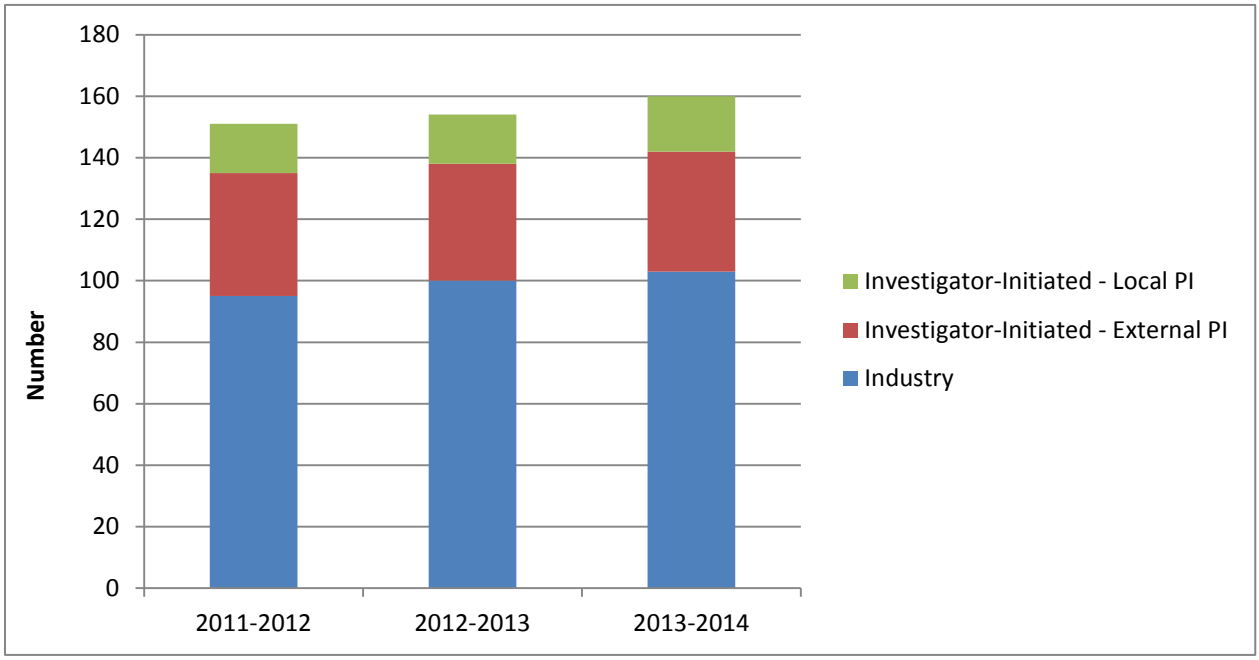
Figure 1. New Studies by Fiscal Year



Active Studies

Studies typically span multiple years so the number of active studies supported by SCPOR in a given year exceeds the number of new studies for the year. Over the three-year pilot period, the number of active studies supported annually by SCPOR grew from 151 to 160 (Table 1, metric A4; Figure 2). Although the number of active studies increased in both the second and third years, the annual increases (2% in the second year and 4% in the third year) were less than the targeted 10%. Over the three-year pilot period, SCPOR supported a total of 236 studies.

Figure 2. Active Studies by Fiscal Year



Active Investigators

The number of principal investigators of clinical studies supported by SCPOR each year grew from 51 to 55 over the pilot period, an 8% increase (Table 1, metric A5). Over the entire pilot period, SCPOR supported a total of 66 principal investigators.

The target for the number of active investigators (metric A5) was to have 80% of the university's clinical investigators supported by SCPOR. It has become clear, however, that the data needed to accurately estimate the total number of clinical investigators at the U of S are not available. As a result, it was not possible to provide reliable estimates for this metric.

However, based on information provided by the U of S Research Ethics Office, it was roughly estimated that SCPOR provides support to approximately 45% of U of S clinical investigators.

Financial Performance

SCPOR's financial performance steadily improved over the three years of the pilot period (Table 1, metric A6; Table 2). Total revenue generated[1] increased by 11% in the second year and 7% in the third year. These annual increases exceeded the target of 5%.

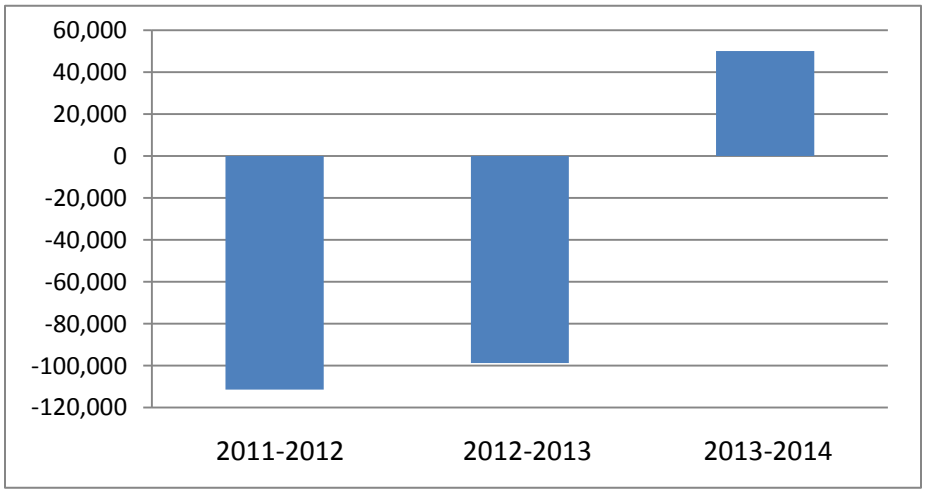
Although SCPOR had a deficit of $111,451 in its first year and a smaller deficit of $98,815 in its second year, it had a surplus of $50,116 in the third year (Table 2 and Figure 3). This improving trend in financial position was due to a progressive reduction in expenses as well as improved revenues.

Table 2. Total Revenue and Expenses by Fiscal Year

	FY 2011-2012	FY 2012-2013	FY 2013-2014
Total Revenue	$810,930*	$770,661**	$857,517
Total Expenses	$922,381	$869,476	$807,401
Surplus/(Deficit)	($111,451)	($98,815)	$50,116

*Includes $92,379 in start-up funding by SCPOR members.
**Includes $22,171 in start-up funding by SCPOR members.

Figure 3. Surplus/Deficit by Fiscal Year



[1] Total revenue generated includes overhead, administrative fees, workshop and symposium revenues and fees for accounting services, CRP consultation services and clinical research nurse/coordinator services. It does not include funding support by SCPOR's members.

Contributing to the increase in operating efficiency was the implementation in FY 2012-2013 of a pool of casual Clinical Research Nurses (CRNs) and Clinical Research Coordinators (CRCs). The pool of casual staff has allowed SCPOR to assign CRNs and CRCs to projects on an as-needed basis without having to carry ongoing salary expenses for staff when they're not needed.

Research Overhead and College of Medicine Salary Support

Important contributors to SCPOR's overall revenue were overhead on clinical studies (typically 30% for industry-sponsored research) and funding provided by the College of Medicine to support the salaries of the Director of Operations, CRNs and CRCs (Table 3).

For the duration of the pilot, SCPOR was allocated the overhead for all clinical studies, including studies for which SCPOR provided full services and those for which SCPOR provided only contract services.[2] The two categories of overhead – full services vs. contract services – are shown on separate lines in Table 3.

Research overhead and the college's salary support comprised 73%, 80% and 67% of total revenue in FY 2011-2012, FY 2012-2013 and FY 2013-2014.

Table 3. Overhead and College of Medicine Human Resource Funding by Fiscal Year

	FY 2011-2012	FY 2012-2013	FY 2013-2014
Overhead from Full Services	$213,207	$206,088	$248,707
Overhead from Contract Services	$124,916	$154,244	$72,305
COM Human Resource Funding*	$255,000	$255,000	$255,000
Start-up Funding	$92,379	$22,171	$0
Other Revenue	$125,428	$133,158	$281,505
Total Revenue	$810,930	$770,661	$857,517
Overhead and COM HR Funding – Percent of Total Revenue	73%	80%	67%

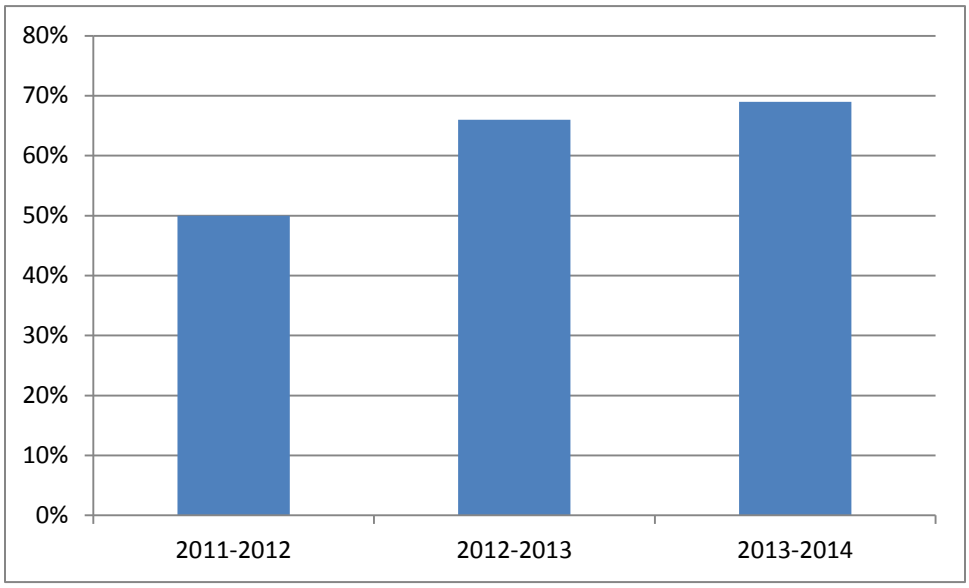
*Funding the College of Medicine provided to support salaries of the Director of Operations, Clinical Research Nurses and Clinical Research Coordinators.

[2] Full services consist of contract negotiation, budget negotiation, ethics submission, application for health region approval and financial services.

Research Participant Enrollment

Success in enrolling participants to studies improved each year over the SCPOR pilot (Table 1, metric A7; Figure 4). The percent of target enrollment achieved increased from 50% in the first year to 66% in the second year (32% increase) to 69% in the third year (5% increase), meeting the metric target of a 5% increase in both the second and third years. These enrollment rates compare well to those reported in the literature.[3]

Figure 4. Percent of Target Enrollment Achieved



Investigator and Coordinator Satisfaction

SCPOR conducted a user satisfaction survey for three weeks in March 2014. Of the 73 investigators and 33 study coordinators (106 total) invited to respond to the survey, 25 investigators and 17 coordinators (42 total) responded – a 40% response rate. Results of the survey showed generally high levels of satisfaction with SCPOR's services (Table 4 and Table 5).

Responses to the survey questions and specific comments made by the respondents lead to the following conclusions:

- In general, satisfaction with SCPOR and its services is high.
- Users feel that SCPOR is important to the conduct of clinical research in the region.

[3] The Center for Information and Study on Clinical Research Participation (CISCRP) reported that enrollment rates dropped from 75% in 2000 to 59% in 2006.

Table 4. Opinion on Services (Percent of Responses)

Statement	Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree	Strongly Agree
SCPOR provides the services I need	0%	0%	2%	5%	12%	43%	38%
SCPOR's assistance is of high quality	0%	0%	0%	5%	17%	44%	34%
SCPOR's assistance is provided in a timely manner	0%	0%	0%	0%	17%	48%	36%
SCPOR is responsive to my needs and requests	0%	0%	3%	3%	13%	40%	43%
The cost of using SCPOR's services is reasonable	8%	3%	0%	34%	8%	32%	16%
SCPOR staff are knowledgeable	0%	0%	0%	10%	5%	41%	44%

Table 5. Overall Satisfaction with Services Received from SCPOR (Percent of Responses)

Very Satisfied	52%
Satisfied	33%
Somewhat Satisfied	7%
Neutral	2%
Somewhat Dissatisfied	5%
Dissatisfied	0%
Very Dissatisfied	0%

- The primary concern among SCPOR's users is cost, particularly the cost of using SCPOR's research nurses and coordinators.
- There are concerns about the speed of the contract negotiation and ethics application processes.

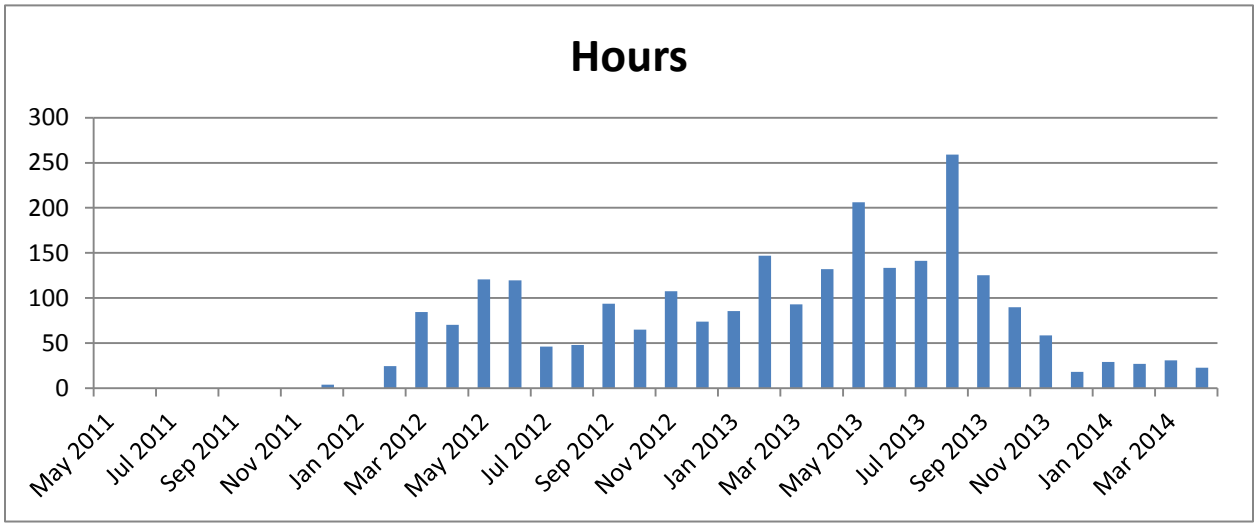
To address concerns revealed by the survey, we are examining how a reduction in fees for research nurses and coordinators would affect SCPOR's financial performance. Preliminary analysis indicates that a 20% reduction in hourly rates would have a small impact (about 2%) on SCPOR's total revenue. In an effort to streamline startup activities and reduce contract negotiation and ethics application times, SCPOR is participating in a national initiative to develop a set of clinical research metrics. SCPOR is piloting the national metrics, making Saskatchewan one of just two provinces participating in the pilot project. The national metrics will be used to benchmark turnaround times for various clinical research activities and will help guide process improvements.

Because user satisfaction was not measured until the third year of the SCPOR pilot, annual improvement (metric A8) could not be assessed.

Clinical Research Unit

Although use of SCPOR's Clinical Research Unit (CRU) at Saskatoon City Hospital picked up in the third year, overall use was well below expectations (Table 1, metric B1; Figure 5). The metric target of a 10% semi-annual increase in room bookings was met in the first half of the second and third years but was not met for the rest of the pilot period.

Figure 5. Hours of Clinical Research Unit Use By Month



A significant obstacle to heavier use of the CRU has been that researchers based at Royal University Hospital have been reluctant to travel to City Hospital to conduct their research. Nonetheless, the excellent suitability of the CRU for conducting clinical trials led to an investigator based in Ellis Hall using the facility for a successful phase I ADHD drug study, contributing to heavy use in summer 2013. The CRU is particularly well situated for researchers at the MS clinic at City Hospital, and those researchers have been among the most regular users of the facility.

In June 2014, the Saskatoon Health Region reassigned four of the CRU's patient rooms to a new convalescent unit, leaving the CRU with just two beds. Despite this reduction in capacity, we continue to carry out a plan to meet with active investigators and encourage them to make use of the excellent facilities available at the CRU.

Patient Experience

A patient experience survey is under development but has not yet been deployed. Therefore, the patient experience metric (B2) is not available for the pilot period.

Training

SCPOR conducted three educational workshops in each of the first two years of the SCPOR pilot, meeting the metric target for those years (Table 1, metric C1). In the third year (May 2013-April 2014), three workshops were scheduled, but because the third workshop was postponed until May 2014, only two workshops were held in the third year and the metric target was not met.

SCPOR published a *Handbook for Clinical Researchers*, meeting the target for the related metric (Table 1, metric C2).

Reimbursement for Research-Related Expenses

Steps have been taken by SCPOR and the joint Office of the Associate Vice-President Research – Health (U of S)/Vice-President Research and Innovation (SHR) to ensure that the Saskatoon Health Region is appropriately reimbursed for research-related costs. All studies are reviewed quarterly for invoicing by the SHR Research Approval Coordinator, and principal investigators (or SCPOR on the PIs' behalf) are invoiced at least annually for study-related expenses. When there are large expenses for a study, the PI is invoiced as frequently as quarterly. For each study, SCPOR sends an annual enrollment update to the Research Approval Coordinator who then determines study-related costs based on the number of participants active in the study. At

the end of a study, the Research Approval Coordinator sends SCPOR a confirmation that all study-related services have been invoiced, that payment has been received and that there will be no further billing for the study from SHR.

Saskatoon Health Region Research Policy Change

In 2014-2015, the Saskatoon Health Region's Research Policy is to be amended to require use of SCPOR's services for reviewing contracts, negotiating budgets, applying for research ethics approval and obtaining SHR operational approval for clinical trials. The new requirement will apply only to physicians new to SHR, i.e., those whose initial appointment to the SHR practitioner staff is after January 1, 2015. Through the use of SCPOR's experienced, trained and certified staff, the policy change is intended to reduce the risk associated with conducting clinical trials.

SCPOR's Future: The Saskatchewan SUPPORT Unit

SCPOR provides one of the key platforms required for the successful application to the Canadian Institutes of Health Research (CIHR) for the creation of a SUPPORT (Support for People and Patient-Oriented Research and Trials) Unit in Saskatchewan. Preparation of the business plan for the SUPPORT Unit is underway. The SUPPORT Unit, which will support patient-oriented research in Saskatchewan, will receive approximately $60 million in funding over five years, consisting of approximately $30 million from CIHR through its Strategy for Patient-Oriented Research matching approximately $30 million in total funds to be pledged by provincial stakeholders, including the Ministry of Health; post-secondary educational institutions and their respective colleges, faculties, and schools; research groups; the Saskatchewan Health Research Foundation and regional health authorities. SCPOR will be an integral part of the SUPPORT Unit and will receive funding through the initiative, putting SCPOR in a strong financial position. Submission of the business plan to CIHR is expected to occur in summer 2014, and funding is expected to begin in winter 2014-2015.

Discussion

Number of Studies

SCPOR had a strong second year, with a 31% increase in new studies over the first year. Despite a decline in new studies in the third year, there was an overall increase of 17% in the number of new studies over the course of the SCPOR pilot. The fluctuation in the number of new studies may be attributed to the business cycle for clinical research in general. Regardless, there are

steps that SCPOR can take to encourage increased use of its services. For example, a reduction in fees for some of SCPOR's services would make those services more affordable for investigators and also might have a positive effect on SCPOR's reputation among researchers, potentially leading to more business. It appears that targeted fee reductions would have a small impact on SCPOR's revenues. Regardless of the fluctuations in SCPOR's business, the impact of the support SCPOR provides to clinical researchers is substantial, with SCPOR having supported 236 studies and 66 principal investigators over the three years of the pilot.

Industry-Sponsored vs. Investigator-Initiated Research

Among studies supported by SCPOR, roughly two-thirds were industry-sponsored and one-third were investigator-initiated. This ratio persisted over the three-year pilot period. All Canadian academic institutions use profits from industry-sponsored trials to augment funding for investigator-driven studies. Investigator-initiated studies are always underfunded (e.g., those funded by CIHR) and require subsidy. Industry-sponsored trials often make a profit (dependent upon meeting quotas for participant enrollment and retention), although in the current global economy profits have dwindled. In its new research plan, the College of Medicine highlights a desire to substantially increase the number of investigator-initiated studies. Doing so, however, will necessitate a commensurate increase in industry-sponsored trials to provide the necessary subsidy.

Participant Enrollment

Enrollment of participants to clinical studies supported by SCPOR showed a very positive trend over the SCPOR pilot, with a substantial increase (32%) in the second year and a smaller increase (5%) in the third year. It is important to recognize that enrollment data are highly variable and the measured rates are likely to vary considerably from sample to sample. Nonetheless, the improving trend in enrollment performance over the SCPOR pilot is encouraging and the rates (most recently 69%) compare well to those reported in the literature.

User Satisfaction

The user satisfaction survey conducted in March 2014 provided valuable information about users' impressions of SCPOR. It was encouraging to confirm that users' satisfaction with SCPOR and its services is high. It was not surprising, based on prior comments made by researchers, that users expressed concerns about SCPOR's costs, particularly the cost of using SCPOR's research nurses and coordinators. This feedback has prompted us to consider reducing SCPOR's fees to address users' concerns and make it easier for researchers to use our services.

Concerns about turnaround time for contracts and ethics applications were also not unexpected. Concerns about turnaround times are widespread across institutions inside and outside of Canada. Regardless, we intend to continue efforts to reduce turnaround times. Participation in the national clinical research metrics program will help us compare our performance against national norms and identify areas in our business processes needing particular attention.

Training

SCPOR has largely been meeting its objectives for training researchers, holding several educational workshops per year and having published the *Handbook for Clinical Researchers*. We will be looking at ways to increase opportunities to train and support clinical researchers.

Clinical Research Unit

Underuse of the Clinical Research Unit has been a significant disappointment over the course of the SCPOR pilot. Despite the CRU's excellent suitability for clinical research, investigators have failed to make use of this first-rate facility to the degree that had been anticipated when SCPOR was established. The main reason for this lack of use has been the reluctance of researchers based at Royal University Hospital to travel to City Hospital to conduct their research. The shortfall in use was undoubtedly a contributing factor in the Saskatoon Health Region's recent decision to reassign several of the CRU's rooms to the new convalescent unit. Regardless, we continue to make efforts to encourage researchers to make use of the CRU. We have recommended to the Health Region that in the fall we have a face-to-face meeting to take stock of the status of research conducted at City Hospital and the College of Medicine's needs for facilities to support clinical research.

Financial Performance and Self-Sufficiency

SCPOR's financial performance steadily improved throughout the pilot, with a reduced deficit in the second year leading to a surplus in the third year. This improving trend was due to both a progressive reduction in expenses and improved revenues. In the third year, revenues increased even though there were fewer new studies that year. The strong third year revenues were due to the large number of studies in the second year and carryover of payments for those studies into the third year. Despite the trend of strengthening revenues, research overhead and College of Medicine financial support were essential contributors to SCPOR's financial position throughout the pilot. It must be recognized that the conduct of clinical research is costly no matter how it is resourced and overhead and salary support will continue to be important. However, given SCPOR's continuing improvement in financial performance

and anticipated funding that will accrue from incorporation into the Saskatchewan SUPPORT Unit, it is expected that SCPOR will continue to progress toward greater financial self-sufficiency.

Metrics

SCPOR had mixed success in meeting its metric targets. For some of the metrics, including numbers of new studies during the second year and enrollment and financial performance over the entire pilot period, SCPOR performed well. For others, such as numbers of new studies in the third year and use of the clinical research unit in general, SCPOR clearly failed to achieve its targets.

One reason for SCPOR's failure to meet targets was that some of the metrics were influenced by factors outside of SCPOR's control. For example, fluctuations in industry demand for clinical research affect several of the metrics and yet are not under SCPOR's control. Another reason for failure to meet targets may have been that some of the targets were unrealistic. For example, a 5% annual increase in the percent of target enrollment achieved cannot be sustained indefinitely (although the target was met during the three-year pilot). Also, a 10% annual increase in the number of active studies (metric A4) would have required an increase in the number of new studies in excess of 30%, clearly an unrealistic target over the long term.

For two of the metrics – investigator and coordinator satisfaction and patient experience – SCPOR did not have the necessary surveys in place in time to provide the needed information. However, a user satisfaction survey is now available and a patient experience survey is under development. For the active investigators target (80% of U of S clinical investigators), it appears that the needed information is simply unavailable.

Even though some of the metrics are influenced by factors that are outside of SCPOR's control, SCPOR must do all it can to strengthen its business and be responsible for outcomes. We intend to continue to meet with and encourage clinical investigators to take advantage of SCPOR's offerings and to take steps to make SCPOR's services more attractive to researchers, such as reducing hourly fees and increasing our training offerings.

We recommend that, during the coming year, SCPOR's management and Members' Executive evaluate the current metrics' appropriateness to measuring SCPOR's performance and consider creating a revised set of metrics that is an improved indicator of SCPOR's success.

The Coming Year

Fiscal year 2014-2015 will be important for SCPOR. Not only will we continue to strive to strengthen SCPOR's services and increase the number of studies and researchers we support but there will be a significant transition as SCPOR becomes part of the Saskatchewan SUPPORT Unit. Incorporation into the SUPPORT Unit will not only strengthen SCPOR's financial position but will expand SCPOR's scope to supporting clinical research across the province. Another important change – the upcoming revision of the Saskatoon Health Region Research Policy to require use of SCPOR by new investigators – will gradually increase demand for SCPOR's services. These changes may necessitate that SCPOR augment its staff to handle an increased workload, and if so, additional office space will be needed to accommodate additional personnel. We look forward to these exciting developments.