

19 JUNE 2023



## Announcing PSP Solutions™



Welcome to the latest edition of PSP Insights™, a newsletter by PSP Solutions™ that aims to keep past, current, and potential future clients up to date

on our team, services, and current hot topics in the industry that relate to Patient Support Programs (PSPs).

This past quarter has been a very exciting one, as we announce the relaunch of our new Waldron & Associates PSP business structure. Although some things at PSP Solutions™ may look a little different, the values of our organization and our commitment to our clients and partners remains the same.

At PSP Solutions™, we are more than just a boutique PSP agency - we become our clients dedicated PSP Support System. As the PSP division of Waldron & Associates we provide consulting services, learning programs, and supportive tools to help our clients achieve PSP Excellence. Our team of experienced and well-established experts within the healthcare industry spans across both manufacturer and provider sides, giving us a comprehensive understanding of PSPs from every angle.

We are committed to guiding our clients along their journey to achieving PSP Excellence. By working with organizations at any and every stage of their PSP lifecycle, from program inception to program conclusion, we help to ensure that they deliver world-class PSPs that meet the unique needs of their patients and prescribers.

At PSP Solutions™, we believe in building long-term relationships with our clients based on trust, transparency, and open communication. We are committed to providing the highest quality support services to help our clients achieve their desired outcomes. Whether you require a quick fix, a short-term project, or a long-term engagement our team is ready to assist you.

As our experts become your PSP Support System, we are equipped to provide tailored solutions that meet your specific needs such as strategic planning, operational support, or tools and training to do it yourself. We have the expertise to help fix and optimize programs when you are experiencing challenges. Our extensive experience in working with over 30 healthcare organizations worldwide has given us unparalleled insights into the ever-changing and complex PSP landscape.

We take a collaborative approach to building long-term relationships with our clients based on mutual trust, respect, and shared goals. Our team is passionate about sharing our expertise and knowledge with our clients and we are committed to helping you achieve success in your PSP initiatives.

We are so excited to finally share this news of our relaunch with our trusted clients and partners. Contact us today to learn more about how we can help you achieve your PSP goals. We look forward to hearing from you!

**Nicole Serena**  
Senior Managing Director  
[nicole@pspsolutions.ca](mailto:nicole@pspsolutions.ca)



## What's Included?

### Highlighting our Expert Team

**PSP Strategic Planning**  
By Sheilagh Commeford,  
Healthcare Consultant

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By Daanyaal Bandukwala,  
Managing Director, Next  
Vision Healthcare Consulting

**Feeling Good about PSP Learning**  
By Rania Cassar-Awe,  
Executive Healthcare  
Consultant

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By Norine Primeau-Menzies,  
Healthcare Consultant

**PSP Solutions™ Services,  
Upcoming Events, and more!**

VISIT OUR WEBSITE FOR MORE INFORMATION ON OUR SERVICES!

## Our Mission

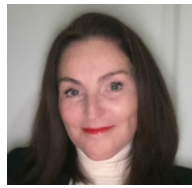
To empower and enable leadership teams, Patient Support Program (PSP) professionals, and organizations within the pharmaceutical and biotech industries to deliver exceptional programs.

## Stay Up-to-Date!

Want to know what we are up to? Visit our website or follow us on LinkedIn to stay up-to-date on our latest offerings and events!



## PSP Strategic Planning



The included quote is one of my favorites on strategy and always reminds me of the importance of thinking ahead, planning, and keeping it simple.

Whether it's in your personal life or in business, the road to success is secured when you have a good plan in place – and a strategy that is executed.

*"Someone is sitting in the shade today because someone planted a tree a long time ago."*

~ Warren Buffett.

Sounds simple but not always an easy task – one that takes time, rigor, discipline, and dedication.

For those who live in the world of PSPs in Canada, there is clear evidence of the role this evolving area has played in navigating through an increasingly complex and cumbersome system. There is a lot at stake – the task of helping patients access new medicines and creating value within the PSP ecosystem.

PSPs have evolved from simply helping patients access a new medicine by providing financial assistance to a suite of strategic services that include clinical care, support to help patients stay on therapy and customizing services to support the patient at every phase of the patient journey.

PSP is at the epicenter of the patient's journey and with the increasing industry need to provide real world evidence is clear; PSP is also well poised to support this important initiative.

We hope to provide you with some guidance on how to build a great strategy for your PSP program, portfolio or one-off plan and deliver sustainable results for the long term and most importantly provide value for our patients, health care practitioners and key stakeholders.

### What is a strategic plan?

- The strategic plan is a process that becomes a planning document. It is a road map that is dynamic and thoughtfully developed to achieve success for your program. The plan can change over time to manage what is occurring in the external environment.

- The plan details the current situation, i.e., where is the PSP program today? Launch, growth phase, facing a new competitor or loss of exclusivity.
- It outlines what will be done in the future, i.e., what would you need to do if a launch date is accelerated OR the program is faced with new guidance from IMC.
- Demonstrate in detail how you will get there – meaning, what is in the plan that outlines how the program will operate to manage and achieve the defined goal, i.e., how the plan will change if you need to launch the program from a regional vs. national approach.

Getting started – keep in mind – it can take a village!

- Gain alignment and buy-in from leadership in your organization that a PSP strategic plan builds out from the core commercial strategy. PSP should have a seat at the table and actively participate in the core strategic planning process and then take time to build the PSP strategy in parallel.
- Secure a planning team, you need subject matter experts to provide guidance and help you build the plan. These could be internal or external experts who will help validate the external environment and your assumptions.
- This is a dynamic process – built into the calendar on an annual basis. The cycle of thinking and planning is ongoing.

### Three simple questions to get the process going.

The planning process with prompt thinking helps you and the team shape the strategy.

- Where are we now?
- Where are we going?
- How do we get there?

Take the time to answer these questions. This will stimulate thinking and the answers will help build the major content required for the plan.

Stay tuned for our next edition for more PSP strategic planning tips!

**Sheilagh Commeford**  
Healthcare Consultant

## What's Trending: Biosimilars



Follow Daanyaal Bandukwala's ongoing conversation with PSP Insight™, as we chat biosimilars and their ever evolving role within the current

pharmaceutical landscape. Read on to find out more!

**PSP INSIGHTS: Where do you predict trends with biosimilars will continue to go this year and beyond?**

With the addition of the Ontario biosimilar policy this year, all the large provinces and territories have some form of a biosimilar policy at this point. This will therefore be a pivotal time for biosimilars in Canada.

We have seen that other regions like Europe and the US are starting to investigate biosimilars as well. Compared to these regions, the policies that have come out in Canada are relatively strict, particularly in terms of their implementation. Previously we have seen that the uptake of biosimilars in Canada has been limited. Therefore, without mandated policies, trends were not showing either biosimilar uptake or the hoped cost saving effect of this uptake. It will be very interesting this year to see if these cost savings come to light, now that mandated switch policies are in place.

Mandated biosimilar switching is likely to have a chain effect within specific therapeutic classes, both this year and in the coming years. With biosimilar pricing down-trending significantly compared to reference biologic pricing, this opens the door for new entrants to come into a specific space. If there isn't a significant level of differentiation, it will be more challenging to get a premium price. There is likely to be a lot of discussion around the effect of biosimilar availability within a therapeutic class, and a comparison against that pricing. This comparison makes the Canadian marketplace a unique environment, which will likely be ongoing for years to come. Any new companies entering the Canadian space will have to consider this differentiation, while existing companies with Canadian launches will have to prioritize where their new products might best fit in. As a result, there is likely to be some key market access implications to come into play in Canada.

**PI: How will the Canadian market continue to differentiate itself from other regions, such as Europe and the US?**

The main difference in the Canadian market is the mandatory switching policies. These policies are not something that you see as widely spread. For example, in Quebec you are seeing a policy which states that as soon as the biosimilar is available, you have six months effective from that date to make that switch from the reference biologic. Furthermore, after that switch period has concluded, in Quebec the branded product is supposed to be delisted, meaning that both physicians and patients have very little access to the branded biologic post switch. This is quite strict and blocks the branded product from that perspective. The strict enforcement of these policies is therefore something that is completely unique to the Canadian market and is not seen elsewhere. As mentioned, when biosimilars were originally launched in Canada, there were no policies and as a result it was very clearly seen that no physician wanted to prescribe biosimilars without some kind of incentive, especially if the brand was still available. Therefore, these policies were created as a need to support a thriving environment for biosimilars as an objective for cost-saving. Moreover, the environment had to support biosimilar companies that were hoping to successfully operate and bring their products to the Canadian market. In the coming years, these policies will therefore create a completely different competitive landscape within Canada, from both the perspective of the reference biologic and the biosimilar.

**PI: In your opinion, who is the most vulnerable during this transition period?**

Any therapeutic area where biosimilars are new is going to be a challenge. For example, in oncology there have been biosimilars for a while. Therefore, the healthcare professionals involved in this field have a different understanding and perspective of biosimilars as they have had more exposure to them. Meanwhile, in other therapeutic areas biosimilars present a first to market strategy.

As a result, there are a lot of big questions from healthcare providers around biosimilars. For instance, questions regarding data and if study findings are representative enough for physicians to make a therapeutic decision are common. This is likely just because physicians in these therapeutic areas are simply not used to the biosimilar ecosystem that they have in place. Overall, even when these policies are out, it will take some getting used to from many perspectives.

**PI: What do you think organizations can do to be best prepared for these changing biosimilar trends?**

From a biosimilar perspective, it is important to remember that many of the current cost of entry points will continue to exist to some extent. Biosimilar companies may not need some of the extensive resources that a large, branded product would require, however in many cases companies will require core resources, like a PSP. If physicians are being mandated by policy, they will continue to expect the same level of service and support for their patients. This may include services such as adherence calls, nursing, ejection services, etc. Therefore, this cost of entry is something that biosimilar organizations should be prepared for.

On the branded side, there are ways to potentially investigate various strategies that support keeping as much market share as possible. This is no doubt a challenging area and will not be easy. However, this strategic investigation needs to be done well in advance before there is even talk of a competitive biosimilar entering the Canadian market. The earlier that a branded company can engage in protecting their share, whether it be from a pricing or new product bundling perspective, will be crucial. Engaging your pair counterparts early on, from a branded perspective, is an essential factor for success.

Stay tuned for Part 3 of What's Trending: Biosimilars, coming in our September issue!

**Daanyaal Bandukwala**  
Managing Director,  
Next Vision Healthcare Consulting



## Do you have a gap to fill in your team or talent?

Introducing PSP Support™ !



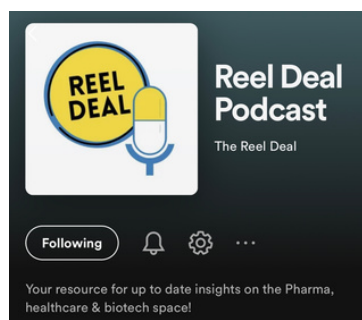
We can provide valuable support to a manufacturer or provider to run their patient support program(s) by helping them design, implement, and evaluate their program so that it meets the needs of patients and provides value to the company.

Designed to help meet the needs of you and your team while managing a talent gap. Our team has valuable expertise and experience, including acting at Director level leadership.

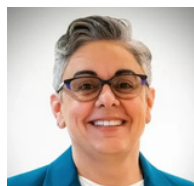
For more information, go to <https://pspsolutions.ca>

## Need Some New Listening?

Announcing the exciting launch of the **Reel Deal Podcast**, hosted by our very own Daanyaal Bandukwala and Nicole Serena! Your resource for up-to-date insights on the Pharma, healthcare & biotech space. Check out the first episode, available now on Spotify.



## Feeling Good about PSP Learning



Ever heard of 70-20-10? That's L&D-speak for how learning happens: 70% on the job, 20% from others, and 10% formal education. HR departments and

Learning and Development teams rightly promote the focus on 70-20-10 for maximum impact on performance development and ROI on learning investment. For those of us working in the fast-paced, rapid growth world of PSP, 70-20-10 may be the secret formula for higher productivity, engagement and competitiveness.

*"By three methods we may learn wisdom: First, by reflection, which is noblest; Second, by imitation, which is easiest; and third by experience, which is the bitterest."*

~ Confucius

We know in our bones that the things we learn through experience (the "70") stay with us. What may go unsaid is the disorientation and anguish that often accompany learning experientially when structure and support are absent - making it the "bitterest" way to learn for Confucius.

Social interactions (the "20") with people who have "been there" eases the pain of learning in the proverbial deep end of the swimming pool. More advanced learners and experts give hope that it can be done, warn you about hidden dangers and share tricks of the trade - implicit knowledge or wisdom that only comes from doing something too many times to count. Learning from others shortens and focuses the learning curve, and enriches the emotional experience of learning, as well as performance.



The final 10% of focus on formal education similarly enables and enhances learning through the other channels. What do we get out of school or university or training? First off, we become aware - expanding the boundaries of our thinking and "knowing what we don't know". Explicit knowledge acquisition in a safe, formal learning environment delivers tangible and intangible benefits: promoting deeper reflection and conceptual thinking, building technical skill sets, growing confidence, easing imposter syndrome, cross-pollinating ideas and practices, and enhancing credibility through credentialing, to name a few. Ultimately, for PSP businesses, relevant formal learning can help colleagues feel like they fit - and show up with confidence and competence faster, especially when married with strategies to improve knowledge application on the job. It's not a one-and-done: studies suggest that by actively linking learning to real-life challenges and spreading learning over time, we can improve knowledge retention and translation substantially (over 50% improvement).

We see the "10" play out in our PSP Learning Institute™ curriculum. PSP Masterclass™ Fundamental workshops demystify PSP for those who are new to the field and intimidated by the complexity of PSPs. Higher level PSP Masterclass™ programs are a bridge to pro-level performance, which is rare and much sought after by manufacturers and PSP providers alike.

A balanced, integrated learning strategy that includes well-timed structured learning opportunities is a time-tested performance acceleration tool that makes learning better and more comfortable. In today's PSP reality of fast growth and even faster staff rotation, learning is much more than a noble pursuit - it's smart business strategy.

**Rania Cassar-Awe**  
Executive Healthcare Consultant

## Privacy Considerations for PSP: 5 Key Components



Privacy can be such a dry topic to read about but in the PSP space, it is necessary to be aware and compliant with applicable Federal and Provincial legislation.

Most organizations that run, or have PSP's, are commercial and fall under Personal Information Protection and Electronic Documents Act (PIPEDA), while some of the PSP stakeholders (hospitals and other public funded institutions) are regulated provincially. Regardless of what legislation applies, the core principles of protecting Personal Information (PI) and Personal Health Information (PHI) are substantively similar. Here are five key components all organizations should have in place:

### Privacy Policy

Every organization should have a comprehensive privacy policy which articulates how the company collects, stores and protects PI and PHI. The policy should also state how customers/patients can access their information and make changes to their information if need be and provide feedback or ask questions.

*"Regardless of what legislation applies, the core principles of protecting Personal Information (PI) and Personal Health Information (PHI) are substantively similar."*

### Privacy Incident/Breach Policy and Procedures

Organizations need to have a policy and process in place to identify privacy incidents, investigate and determine if a breach has occurred, and mitigate the risk of future breaches. Additionally, the process needs to include reporting or disclosing breaches to affected parties and if need be, to the appropriate Privacy Commissioners' Office.

### Privacy Training

All staff should be trained on the privacy policy and privacy breaches. Training can be dry and hard for staff to follow so including real life scenarios from past incidents can go a long way to making this real for staff. Training should be done annually and records kept.

### High Risk Process Data Flow Analysis

Documenting the data flows for high-risk processes in a business is a way to demonstrate a higher standard of due diligence. Documented data flows can be done for any processes but is usually reserved for a few scenarios:

- Processes where there is higher sensitivity data collected (PHI or financial data for example), or
- Processes where there is a higher risk of privacy breaches (prior breaches have happened).

Documented data flows are analyzed to ensure risk is minimized, resulting in a safer practice overall.

### Privacy Impact Assessments

Businesses that collect and store PI and PHI need to be systematically documented and analyzed to ensure data collected is appropriate and risk is minimized. Privacy Impact Assessments are the standard in the industry and more and more an expectation by regulators. While they are complex and take time to complete (because they cover off many processes within a business), in the event of a significant breach, regulators will be looking to ensure the business has undergone the appropriate due diligence.

Ensuring that the above core components of any privacy function are in place will serve you well in your company and demonstrates you have done the due diligence required to protect your customers/patient's information. If anyone has questions or would like more information on how PSP Consult™ can help you develop, or shore up your privacy function, please let us know.

Best wishes for PSP success!

**Norine Primeau-Menzies**  
Healthcare Consultant



## New Service Alert: PSP Expert™ is Here!

### Speaker Engagements:

We can present on various topics with respect to PSPs.

### Advisory Boards:

We can participate on advisory boards.

### Podcasts



**PSP Expert™**

## Introducing the New PSP Learning Institute™!



If you are looking to build PSP knowledge, skills, and confidence, our PSP Learning Institute™ and it's comprehensive learning programs can help you achieve these goals. We are the only company, globally, that supports PSP professional growth through our certified learning programs.

### Our services include:

- PSP Certify™
- Introduction to Risk Management™
- PSP Coach™
- Navigating the PSP™
- PSP Fundamentals™ Workshops
- PSP Masters™ Workshops
- PSP Providers Learning Series™

Want to find out more? Check out our website at [www.pspolutions.ca](http://www.pspolutions.ca)



## Introducing PSP Toolkit™!

At PSP Solutions™, we understand the challenges that pharmaceutical and biotech professionals face in developing, implementing, monitoring, and managing issues across their PSPs. That is why we have created the PSP Toolkit™, a comprehensive suite of resources to support you and your efforts to streamline your PSP processes and drive exceptional outcomes.

Our mission is to provide PSP professionals in the pharmaceutical and biotech industries with the tools they need to achieve operational excellence in their Patient Support Programs. Whether you are a seasoned veteran or new to the field, the PSP Toolkit™ offerings were designed to support you with the essential resources you need to succeed. Our team of experts have meticulously crafted the PSP Toolkit™ to ensure that our offerings help to streamline your PSP processes to make sure that every aspect of your PSP program is of the highest quality. From program design and implementation to monitoring and evaluation, we have you covered. Our PSP Toolkit™ offerings are designed to be flexible to your needs. Our team is available to incorporate these tools when we work with clients, or clients have the option to utilize the PSP Toolkit™ resources on their own. Our toolkit is continuously updated to reflect the latest industry best practices and regulatory requirements, keeping you ahead of the curve!

For more information, contact us today or visit our website at [www.psp-solutions.ca](http://www.psp-solutions.ca)

## Showcasing our New Business Structure!

waldron & associates



**PSP** Consult™

**PSP** Toolkit™

**PSP** Learning Institute™

\*Formerly The Cadence Learning Company



## What's Next?

*Stay Tuned for Our Upcoming PSP Inner Circle™ Events!*

**PSP Finances: Invoice Reconciliation**  
Jul 17, 2023

**Market Access: Guest Speaker**  
Aug 14, 2023

**The Future of PSPs: Guest Speaker**  
Sept 15, 2023

**PSP Strategic Planning**  
Oct 13, 2023

**Audit Readiness**  
Nov 17, 2023

**Preparing for the Year Ahead - 2024**  
December 15, 2023

*And more to come in 2024!*

*Stay tuned for our next newsletter to learn more about how we are working to seamlessly deliver PSP Solutions™ to meet all of your PSP needs!*

[WWW.PSPSOLUTIONS.CA](http://WWW.PSPSOLUTIONS.CA)