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THE GNARLY DILEMMA – TO LAUNCH OR NOT¹

“We’re in the midst of a transition that’s a little gnarly right now and we’ve got to chart our way through that in the most sustainable way possible – it’s not an easy task” - Bill Lumbergh

Bill Lumbergh, Sr. Director of Product Strategy for Helios, peered through the window after a review meeting for the latest release of the company’s flagship software TPS SOLUTION. During this meeting, major product issues were revealed which could put the reputation of Helios at risk and, potentially, harm patients receiving radiation therapy. Bill and his software teams had embarked on a complete redesign of TPS SOLUTION’s architecture. The redesign, which had starved TPS SOLUTION’s customers of new features for the past 18 months, was now behind schedule.

Helios’s customers were Radiation Oncology departments that treated cancer patients with controlled radiation from linear accelerators. These complex machines required diligent quality assurance checks to ensure patients were treated correctly and not harmed. Radiation oncologists depended on TPS SOLUTION software to prevent potentially lethal radiation effects. With no margin for error, Bill knew they needed to get it right.

Key to “getting it right” meant designing a software development and delivery process that minimized *even the possibility* of an error occurring in TPS SOLUTION. To achieve this, Bill had to unite the disparate components of the existing TPS SOLUTION product into a single, comprehensive, code base. A single code base would have reduced complexity and allowed Helios to bring more software features to the market faster, but required changing to a Software-as-a-Service (SaaS) delivery model.

Switching TPS SOLUTION to a single code base SaaS product meant Helios’s customers required internet access and Windows Server 2019. Customers would have needed to upgrade TPS SOLUTION, upgrade the operating system of their TPS SOLUTION servers, and get permission to place the server online from Hospital IT security. The redesigned TPS SOLUTION would have placed a significant burden on customers.

Should Bill release the current design and risk the reputation of Helios? Should he re-design it to please more customers but delay the project further, possibly causing the development team to rush and have a calculation error?

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The Healthcare Information Technology Industry

Healthcare information technology encompasses the solutions of systems for storing, retrieving, sharing, and analyzing patient medical-related data. Modern medical professionals continually seek innovative solutions to provide higher-quality care, improved diagnostics, and more accurate reporting results. These solutions were designed to make sure healthcare providers were able to make critical medical decisions using the most accurate and up-to-date information possible. The use of information technology systems in the healthcare sector has been proven to significantly improve the quality of care and accuracy of diagnostics. (Patric, 2022)

The sale of medical devices has grown at an unprecedented rate over the past decade. The number and complexity of the devices on the market have risen significantly, too. This rapid evolution has delivered life-enhancing innovations particularly in the Oncology field. The industry's transformational growth and innovation have placed new burdens on software systems. Quality issues rightly concerned every stockholder in the medical device chain, from manufacturers and regulators to payors, doctors, and patients. The medical device industry was approaching a point where the increasing likelihood of a quality event, the rising costs associated with such events, and the public nature of quality performance would force companies to force medical device reliability through product design and the most cutting-edge software applications.

The hardware design necessary for processing patient data required connecting separate components and developing software solutions to analyze the diagnostic details and distribute the patient data efficiently and flawlessly. Much of this software was deployed using SaaS and was a rapidly growing facet of the healthcare industry. In a simple definition, SaaS was software that was licensed on a subscription basis. Since 2012, the rate of SaaS in healthcare had increased by over 20% each year. By the year 2026, the United States value of SaaS solutions was anticipated to exceed \$52 billion USD. Globally, SaaS was expected to reach over \$37 billion USD by the year 2026. The United States was the world's largest SaaS market, while China boasted the fastest growth rate. This rise in the number of organizations adopting these SaaS solutions was the catalyst that led to increased growth and revenues. (Folio3, 2022)

The advantages of SaaS versus traditional software are illustrated in Exhibit 1. Traditional software was typically purchased with a one-time fee, usually limited to one device, and required updates installed by the user. SaaS software could be used across multiple users and devices, and updates were deployed instantaneously as needed by the software developer. This was advantageous to the SaaS user, ensuring the latest technology was utilized and the best possible service and outcomes for patients was provided. The disadvantage existed when the end users had outdated or incompatible server platforms to deploy the updates, as seen in this case with TPS SOLUTION.

The Healthcare Industry was facing continued challenges in managing data growth, improving patient care and outcomes, and compliance with security and privacy issues. Specific to radiation treatment in the Oncology field, new technology was essential for quality assurance to ensure a consistent and safe treatment dosage at the target volume while minimizing dosage to the normal tissues and minimal exposure to medical personnel. The Healthcare Industry had an ongoing necessity for modernizing Information Technology and updating its architecture for continued success.

About Helios

Helios provided innovative solutions for Radiation Therapy and Diagnostic Imaging centers. The organization's "...mission is to enable healthier lives by improving the avoidance, detection, and treatment of cancer." More than 5,000 cancer centers worldwide relied on Helios for independent, integrated Quality Management. With a focus on ongoing support, Helios aimed to ease technology adoption, enhance workflows, and improve outcomes so that healthcare providers could achieve tangible results for Patient Safety. (BigTech Technologies, 2022) Helios aspired to improve the avoidance, detection, and treatment of cancer to enable healthier lives. Their solutions were utilized in more than 50 countries worldwide and were present in over 80% of US cancer treatment centers and over 60% of global cancer treatment centers. (BigTech Technologies, 2021)

Origins

Helios was founded in 1984 as a calibration facility. Following an EPA grant for radon monitor development, Helios introduced 'At Ease,' the first continuous radon monitoring device, in 1986. (Initech Corporation, 2022) Helios continued to innovate in the medical radiation monitoring and treatment space and was the first to market multiple products and solutions. Tom Brady, founder of Helios's medical device business and current CSO, stated, "My passion for measurement innovation and product ease of use in radiotherapy quality spans over 44 years. Over those decades, the rapid technological evolution of radiotherapy delivery methods presented treatment safety challenges to clinical physicists. Developing and providing Helios solutions to those ongoing challenges has led to improved treatment technologies and safety, positively impacting countless patients, which has been very rewarding." (BigTech Technologies, 2021)

How Does Helios Make Money?

Helios sold both hardware and software that was utilized by radiation therapy and diagnostic imaging centers for providing quality assurance testing. Helios's main product, TPS SOLUTION, was software that was sold directly to a customer and then supported by an annual service agreement. As updates and improvements to the software became available, Helios would sell those upgrades to the customer. Later in this discussion, we will highlight the opportunities and challenges to evolve the selling structure and software delivery of TPS SOLUTION to meet new industry standards and create a tool that would generate more consistent annual sales.

BigTech Acquisition

On January 7, 2021, BigTech Technologies announced they had purchased Helios Corporation. The acquisition was labeled by BigTech leadership as a natural progression in upholding BigTech's mission to harness its unrivaled knowledge of ionizing radiation for the greater good of humanity. Additionally, the acquisition was consistent with BigTech's strategic expansion focused on building its portfolio of industry-leading technology solutions across a range of core and adjacent markets. After the acquisition of Helios, in October 2021, BigTech Technologies Inc. went public on the New York Stock Exchange by merging with a Goldman Sachs backed SPAC.

Helios Products and Solutions

Helios provided numerous products and solutions that were designed to increase safety for patients and staff in areas where radiation was delivered. The overall product offering from Helios was a blend of hardware and software. For this case, we focused our discussion on a product that was designed around

patient and machine quality assurance. The product, known as TPS SOLUTION, was the largest product offering in terms of market share and sales for Helios.

TPS SOLUTION software provided quality assurance metrics in two different areas of focus, patients, and machines. For patients, the product was software that validated the treatment plan for delivering radiation to a targeted area within the body where a cancerous tumor resides. The plans were validated to ensure that the maximum amount of radiation was delivered to the tumor, while sparing as much of the tissue surrounding the targeted area from large doses of radiation. The plans were created by dosimetrists and physicists. Radiation treatment plans are known to be extraordinarily complex and tedious. If treatment was not meticulously planned, the outcomes could be more dangerous or deadly than cancer itself. TPS SOLUTION was designed as a final check for quality assurance to help prevent human error.

On the machine side, the TPS SOLUTION software automated the direct collection of daily quality assurance metrics necessary to ensure the equipment delivered the correct radiation levels to a specific target. These quality assurance tests and metrics were previously acquired through arduous work done by physicists. TPS SOLUTION software was designed to simplify the quality assurance process and take the human element out of the process, which could help eliminate human error while saving time and money.

The TPS SOLUTION product was sold as software that could be deployed on a customer's own server hardware. Helios also offered the option of allowing customers to purchase Helios hardware. The complete solution of hardware and software allowed the customer to optimize the full potential of the product offering while eliminating potential service issues that could arise when troubleshooting issues between software and hardware.

Helios's Competition

Helios was the first to bring to market software used for quality assurance in diagnostic imaging and radiation oncology in 1996. The company quickly grew and became dominant in the industry, with over 90% market share in the United States and over 85% market share worldwide. The primary competition for the TPS SOLUTION product is physicists who maintain equipment and do manual quality assurance testing in the same manner it was done before TPS SOLUTION was released. This competition was limited by the increasing demand for physicists in healthcare and the diminishing number of physicists available. A few small companies and the large linear accelerator (LINAC) companies have tried to develop and sell their own solution but failed to successfully penetrate the market. The barrier to entry among the smaller companies was the financial investment needed to produce a product as large in scope and technically advanced in its offering as TPS SOLUTION. For the big LINAC companies, the market demand for solutions to quality assurance are independent of their LINACs core offering. The requirement of a third party to do quality assurance validation was similar to the reason publicly traded companies are required to use auditors to review and certify their accounting prior to posting to investors.

Helios's Technology

TPS SOLUTION was an integrated, independent Patient and Machine Quality management software for radiation therapy. Radiation oncology departments are busy. In pursuit of Patient Safety, medical physicists manage complex processes, complicated machines, and high expectations for overall treatment quality. TPS SOLUTION simplifies and standardizes how they balance it all – with full integration and independence intact. Most quality assurance (QA) programs consist of disconnected tools and data repositories (devices, spreadsheets, binders, databases, etc.). This could lead to de-centralized operations, process inefficiency, training gaps, and redundant support contracts. The TPS SOLUTION technology

allows verification and tracking of dose throughout the treatment course to catch errors; manage patient and machine QA in the same place to save time and reduce the likelihood of undetected errors; cut time consumed by manual tasks; eliminate the need for multiple applications. Single-LINAC centers and multi-center networks use the TPS SOLUTION Platform to reduce process steps, produce clear results, reduce machine downtime, and generate reports for easy reporting and compliance.

TPS SOLUTION brought consistency and convenience to critical tasks within a common framework and operated on a single database. It was designed from the ground up to support the real world of radiation therapy – where every combination of Oncology Information Systems (OIS), Treatment Planning Systems (TPS), linear accelerator (LINAC), and clinical implementation was unique.

Software Development at Helios

Helios, for most of its lifespan, had been a hardware company, inventing and manufacturing machines. Developing and selling quality assurance equipment such as a 2D array of Diodes that measured machine outputs is what Helios became famous for. Helios had some experience developing software, however, it was only software to run their hardware equipment. TPS SOLUTION was the company’s first endeavor into a true, enterprise-level software product that would run on a centralized server.

Siloed Business Units – The Old Model

Helios’s business units were divided up into individual business units as Radiation Therapy Measurement (RTm), Radiation Therapy Alignment (RTa), and Radiation Therapy Software (RTs). Each business unit worked in a silo, each working on their own products for their own customers. The siloed organization applied to the software development teams and processes as well. This meant each software team worked independently developing standalone software for their business unit. For example, the software engineers in the RTm unit did not interact with the software engineers in the RTs unit. The siloed nature of the software development process meant each software team spent little time or effort ensuring their software would integrate or cooperate with the other software developed at Helios.

TPS SOLUTION was meant to integrate with several hardware devices, each of the devices also had corresponding software to ‘run’ that device. Since the team working on the RTm software did not work with the RTs software, significant issues arose. For example, changes made to the RTm software, could cascade errors in the RTs software. This was a significant source of concern for Bill and a considerable time sink for his software teams. To correct for these failures Bill realigned the siloed teams into a single software development team.

Re-organizing & Innovation Structure

After Helios was acquired by BigTech Technologies in January of 2021, Bill Lumbergh was promoted to Director of Product Strategy on March 10th, 2022. Before joining Helios, Bill was the Director of Product Management at TomoTherapy/Accuracy for Treatment Planning and Data Management, Product Manager at Philips for Treatment Planning, and Product Manager at Nicolet Biomedical. Before formally moving into product management, Bill had roles in server and support, applications, and sales. Bill started as a Biomedical Engineer in a United Kingdom National Health Services hospital. “Bill’s industry and professional experience, as well as his contributions at Helios, make him uniquely qualified for this important leadership position,” said the President of Helios.

In Bill's former role, he led the RTs product management team which included product managers, clinical collaborations specialists, clinical physicists, requirements analysts, and a user-interface, user-experience (UI/UX) designer. Bill retained his leadership responsibilities for those roles and gained the Director of Product Management, the Senior Manager of Business Intelligence and Product Strategy, and the Marketing and USA Sales Director of Marketing. These changes were aligned with Helios's strategy to transform from a Business Unit focus to Integrated Hardware and Software solutions focused product strategies. The product strategy team would centralize and lead Helios's market-driven planning, product management, product definition, and server as product owner for project execution, as well as lead the commercial launch process.

In conjunction with Bill's promotion, all software development was united into one single entity made up of the TPS SOLUTION developers and the software development teams for the hardware products. To move to a SaaS model, a new SaaS software architect and development team were brought into the company in 2020. Their goal was to release TPS SOLUTION as a SaaS offering in nine months. This did not materialize, and the initial release was delayed until April 2022. The SaaS team worked independently of the larger, united team, and rarely engaged or collaborated with the experienced 'On-Premises' software engineers. The SaaS team was not aware of the non-functional requirements, and this resulted in the design and development of a software solution that included major gaps in coverage for existing customers.

Gaps in the New Design

On Wednesday, August 3rd the design review to determine the path to move current customers from version 3.x to 4.1 took place, and it was very contentious. During this meeting, the gnarly reality of the situation became apparent. The design the SaaS team created added new costs and IT security demands to the customers. Furthermore, the new design did not address the requirements of the existing customers.

The new design required all TPS SOLUTION servers to have internet access so that code could be pushed and managed via the internet. To implement this design, all existing customers would need to get permission from their IT security department to grant internet access to their servers running TPS SOLUTION. This task would most likely require Helios resources to complete additional security risk forms for each site that did not have internet access, an estimated to be 80% of all users.

The new software design will only work on Windows Server 2019. More than 50% of TPS SOLUTION's customers were running the software on an older and now incompatible version of Windows Server. To implement the new TPS SOLUTION software, those customers would need to upgrade their server operating system, which is estimated to cost approximately \$972 (Microsoft Corporation, 2019) Additionally, updating the server operating system will require an additional IT project on top of the TPS SOLUTION upgrade project. See Exhibit 4.

Lack of Distributed Servers

Many of the most recent TPS SOLUTION customers employed an environment consisting of a database server and one or more job/application servers. The job/application servers contained expensive Graphical Processing Units (GPUs) to rapidly process the 3D dose calculations needed by TPS SOLUTION. Utilizing job/applications servers enabled customers to scale up processing to account for many patients and many calculations. The new design did not take this requirement into account, which represented a major oversight. Customers who employed a GPU enabled architecture would not be able to upgrade to

the latest version of TPS SOLUTION. New customers would not be able to utilize GPUs to scale up their operations with the latest version of TPS SOLUTION.

Data Veracity on Current customers

“What it comes down to, the biggest hurdle is true knowledge of our installed base,” noted Bill. Knowing what was going to be acceptable to the current base was necessary if Bill were to choose to phase in the 4.1 upgrades. Unfortunately, the available data on the installed customer deployment base was not detailed nor thorough enough to provide insight. Bill and Helios simply did not have the right information to make a data-driven decision. See Exhibit 2.

The Gnarly Question

As Bill sat in his office before his next design meeting with his staff, he realized that there was not enough time to develop the next version of TPS SOLUTION that would meet all Helios’s customers’ requirements. It was August, and management wanted the next release of TPS SOLUTION unveiled at the important American Society for Radiation Oncology (ASTRO) Conference in October. Bill needed to make a decision that provided customers with the new advancements and features that TPS SOLUTION was known to deliver every year while also delivering a product that could be delivered in a manner that meets the customer’s deployed architecture. While delivering on customers’ expectations, Bill needed to deliver Helios’s directive that transitioned customers from on-premises hardware and software to enterprise software that deployed as a SaaS solution via cloud servers. Bill had come to the realization that he had three choices:

Choice #1 - Continue

Continue to develop the next generation of TPS SOLUTION with a single code base and unveil it at ASTRO.

The benefits were that the design team was already developing this new solution. It met the company’s plans of delivering TPS SOLUTION as a subscription which would allow the company to generate more consistent revenue on an annual basis. The new SaaS would also make it easier to roll out future updates/upgrades to customers as all customers would be operating on the same software version.

The negative was that most of Helios’s customers were not ready and might resist moving to this new architecture. Most customers had their own servers and software residing in their buildings. Customers like to have control of their data, and many IT departments had security concerns with data going to cloud services. These hurdles could lead to a decline in revenue that is typically generated from these annual software updates.

Choice #2 - Delay

Delay the release of the new software until Bill’s software team can develop a solution that could meet the architecture currently in place for most customers and provide new features that could be deployed for both versions.

Delaying the release by a couple of months would give the team more time to develop a solution that could be used by current customers while also giving both new and existing customers the option to move to the new SaaS solution. This would allow Helios to generate the revenue that is typically associated

with these new releases. Even though the software was delayed in its release, Bill's team could still work with marketing to present the future release at ASTRO.

The negative was that the team would again be split to develop new software for two different platforms. Splitting the team would cost the company time and money. This would slow the progress of getting customers to adopt the new SaaS model, affecting the long-term sales strategy and the ability to deliver the latest updates to the customer base quickly.

Choice #3 - Stop

Stop development of the new platform temporarily and concentrate on the continuous delivery of new features for the existing solution. This would allow Bill's software team to quickly develop new features and tools that the customer base requires.

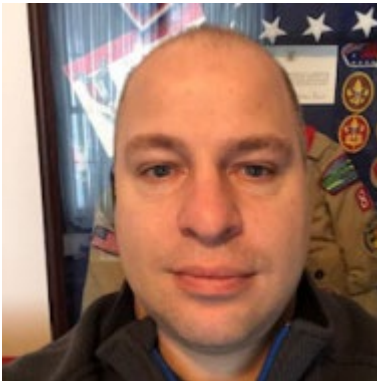
The new revision could be built in a couple of months and be unveiled at ASTRO which the customer base is accustomed to seeing. This would allow for marketing to engage with customers at the conference and educate them about the benefits of the new SaaS platform that was in development for future release.

The negatives were that the development and deployment of the SaaS version was delayed, delaying the additional revenue associated with the SaaS sales model. The backtracking to the development of new features for an old platform came at a cost to the company and lost development time for the software team. The company would have to fund the development of a new release on the old platform while simultaneously funding the development of the SaaS platform.

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Biographies



Jerret Giammichele is the account manager in Precision Diagnosis Solutions for Philips Medical Systems. He has been recognized within Philips Medical Systems as being among the elite top 5 percent sales representatives in the entire organization. He is skilled in MRI, medical devices, urology, neurology and capital equipment and has more than 20 years of award-winning sales success. Giammichele received a bachelor's degree in business administration from the State University of New York College at Fredonia.



Pilip Haurysheu is the founder/developer of INeedHelpBy, a nonprofit initiative devoted to providing emergency help to victims of political persecution in Belarus. He also serves as a pathologist's assistant at Moffitt Cancer Center and has experience in pathology at Thomas Jefferson University Hospitals and Massachusetts General Hospital. Previously, Haurysheu was the medical examiner for the State Division of Forensic Medical Examinations, Regional Department of Minsk and Minsk District. Haurysheu earned an MD from Gomel State Medical University.



Nathan Pell, a solutions architect at BigTech, leads the global IT sales effort for radiotherapy QA enterprise software solutions. His objective is to ensure the client is set up for success with their system architecture and deployment processes. He has spent a decade in radiation therapy positioning sales and prior to that, he was a high school physics teacher in Orange County, Florida. Pell received a bachelor's degree in applied physics from East Carolina University and has participated in the Sales Mastery Boot Camp, a SPIN sales training course and a Huthwaite Professional Sales Skills training course.



Marissa Shearer started working for Commercial Risk Management, Inc. while in high school and now serves as executive vice president. She oversees the entire staff to ensure the organization adheres to the regulations and guidelines set by the state of Florida to guard against non-compliance penalties. She monitors Commercial Risk Management Inc.'s internal and external financial obligations and oversees the quantitative analysis of clients' programs using interactive reporting systems. Shearer received a bachelor's degree in English with a concentration in Literature from the University of South Florida.

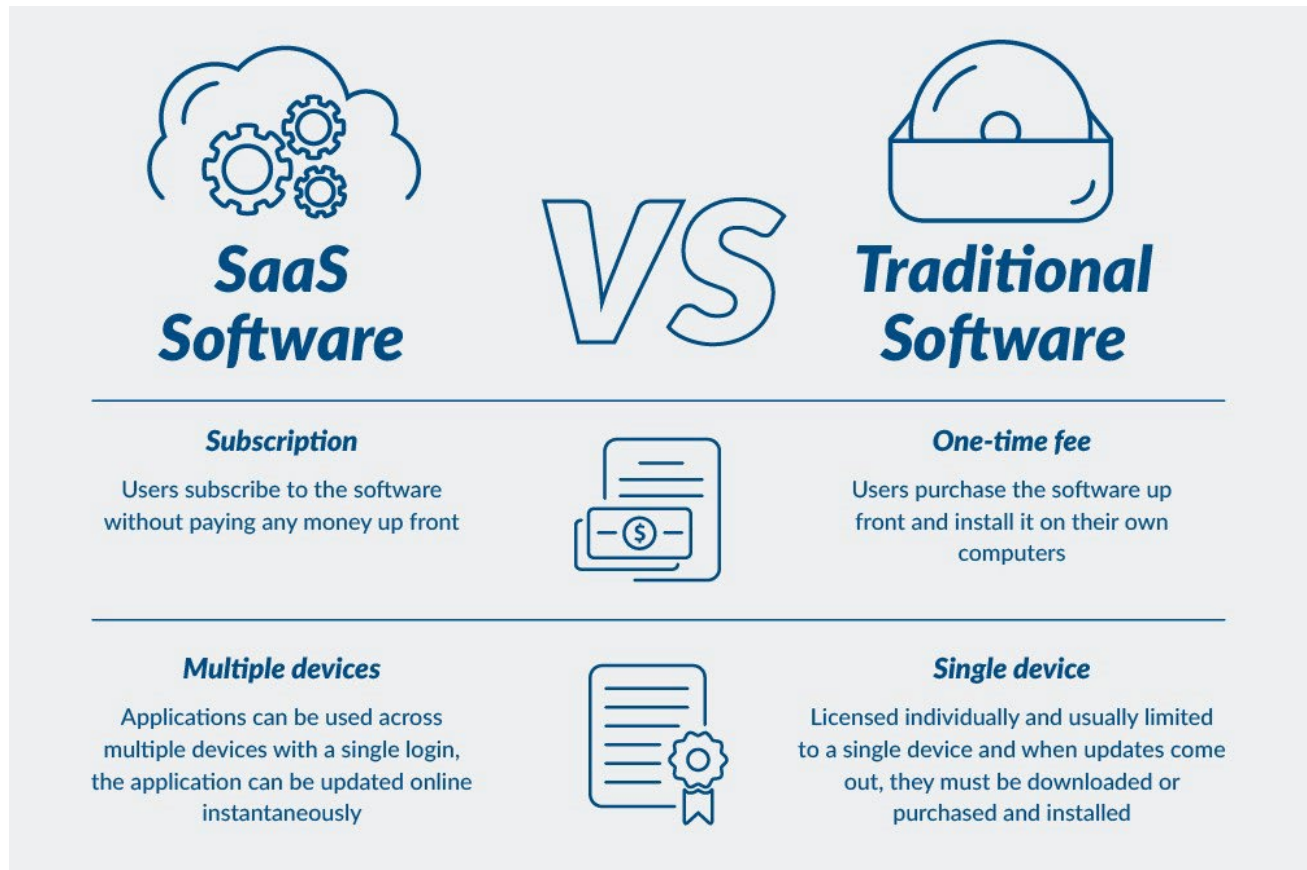


Christopher Streich has spent his career working in intelligence, ranging from military intelligence to his current position of artificial intelligence/machine learning program manager at Accenture Federal Services – Emerging Technologies. In this role, he leads applied artificial intelligence and machine learning development. Streich is a former U.S. Army Intelligence Officer and continued to work afterwards in the intelligence community and in corporate security as an investigator. Streich earned a master's degree in applied urban science and informatics from New York University and a bachelor's degree in economics from the University of Montana.



Kevin Thomas is the senior manager of grower relations with Florida's Natural Growers, a grower-owned agricultural cooperative. He is responsible for the interactions between the co-op members and the plant operations, including coordination of harvesting and procurement of fruit to meet annual sales forecasts. He also represents Florida's Natural Growers in numerous trade groups and serves on several industry boards. He has spent his entire career – more than 25 years with the organization. Thomas received a bachelor's degree in business-citrus from Florida Southern College.

Exhibit 1: SaaS vs On-Prem



(Atlantic.net, 2022)

Exhibit 2 TPS SOLUTION Installed Base Environments Sample Data Set

Server 2016	Windows Server 2016 64-bit	Windows server 2016 Standard	2012 R2	2012R2
2016	2016 server	2016 Standard	2016 Std	2019
2019 Server	2019 Server OS	2019 server standard	2019 Standard	2019 std
7 embedded	Embedded	Microsoft server 2016	Microsoft Win Server 2019 standard	Microsoft Windows 10 Pro
Microsoft Windows 10 Pro for Workstations	Microsoft Windows Embedded Standard Service Pack 1	Microsoft Windows Server 2012 R2	Microsoft Windows Server 2016 Standard	Microsoft Windows server 2019
OS Microsoft Windows 10 Pro	Server	Server 16	Server 2012	Server 2012 R2
Server 2016	Server 2016 Standard	Server 2016 STD	Server 2019	Server 2019 OS Std
Server 2019 Standard	Server 2019 Std	Services	Win 10	Win 10 Pro
Win 2019 Server	Win 7 embedded	Win 8 Pro	Win 8.1	Win Server 2008 R2 Standard
WIN10 PRO	Win7 embedded	Wind server 2016 Standard	Window Server 2019	WINDOWS 10
Windows 10 (20H2)	Windows 10 Enterprise	Windows 10 Pro	Windows 10 Pro 1709	Windows 10 Pro 1803
Microsoft Windows 10 Pro for Workstations	Windows 10 Pro x64	Windows 10Pro	Windows 2012 R2	Windows 2016

(Fuller)

Exhibit 3 Windows Server 2019 Pricing

Licensing Windows Server 2019

The operating system that bridges on-premises and Azure services

Overview of Windows Server 2019

Windows Server 2019 is the operating system that bridges on-premises environments with Azure services, enabling hybrid scenarios that maximize existing investments. Increase security and reduce business risk with multiple layers of protection built into the operating system. Evolve your datacenter infrastructure to achieve greater efficiency and scale with Hyper-converged Infrastructure. Enable developers and IT pros to create cloud native applications and modernize their traditional apps using containers and micro-services.

Unique hybrid capabilities with Azure	Advanced multi-layer security	Faster innovation for applications	Unprecedented Hyper-Converged
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Windows Server 2019 editions

The right edition for your organization size, datacenter, and virtualization requirements.

Editions	Description	Licensing model	CAL requirements	Pricing
Windows Server 2019 Datacenter	For highly virtualized datacenters and cloud environments	Core based	WS CAL	\$6,155
Windows Server 2019 Standard	For physical or minimally virtualized environments	Core based	WS CAL	\$972
Windows Server 2019 Essentials	For small businesses with up to 25 users and 50 devices	Specialty server	No CAL required	\$501
Microsoft Hyper-V Server 2019	Free hypervisor download.	N/A	N/A	N/A

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(Microsoft Corporation, 2019)