

 solventum | Medtronic



Call it Genius
Collaboration that inspires

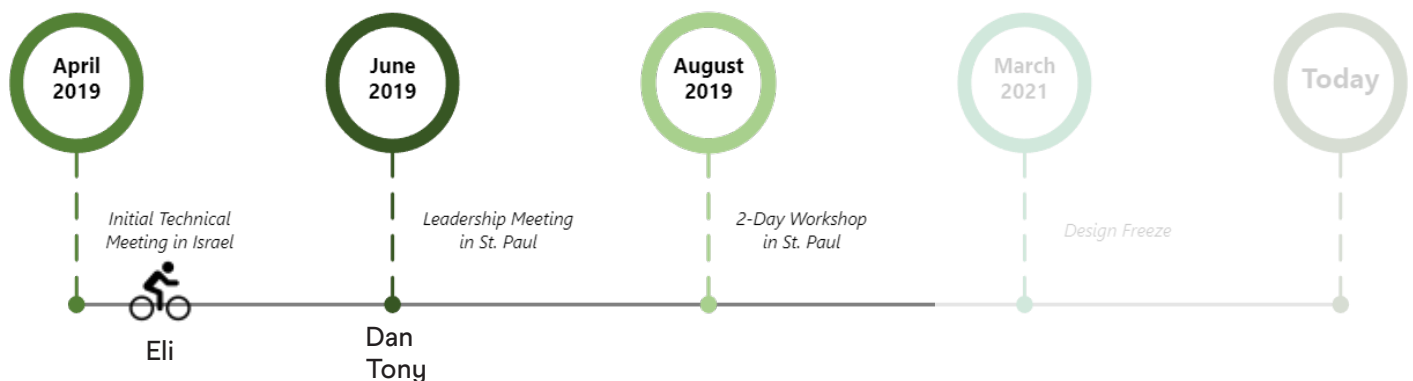
Genesis

How it started

During a visit to Israel, Del Lawson, Solventum R&D Director, found himself in an engaging discussion about technology and materials with Ophir Zamir, former Medtronic Director of Product Development & Artificial Intelligence. The initial meeting sparked an immediate technical connection, prompting Zamir to introduce some key members of his team, including Eli Ziv, Medtronic V&V Manager, to the conversation. The atmosphere was charged with potential as ideas flowed seamlessly among the group.

Following this encounter, Lawson shared the outcomes with his Solventum colleagues, Dan Durenberger, Global Strategic Accounts, and Tony Kaufman, Sr. Business Development Manager, highlighting the promising collaboration he had observed. Recognizing an opportunity, Durenberger quickly reached out to Laurence Keselbrener, former Vice President Given Imaging Medtronic Israel, and set up a meeting at their customer innovation center during one of her visits to the Twin Cities. There was an unmistakable sense of excitement, as both companies realized they were on the brink of a productive partnership. They also acknowledged the enormity of the challenge ahead, humorously dubbing the program “Mission Impossible” due to its ambitious nature.

Despite being large, complex organizations, both companies demonstrated remarkable decisiveness and adaptability. In just over a month, they orchestrated a workshop, bringing together key players from both sides. This workshop served as the pivotal moment, solidifying a foundation for the working relationship that would flourish into a lasting friendship.



Capsule endoscopy

Given Imaging, an Israeli startup established in 1988, invented capsule endoscopy and is now a market leader in this field. The FDA and CE approved their innovative PillCam™ Products, such as Small Bowel, Colon, and Crohn's Disease capsules, in 2001. Acquired by Covidien in 2014 and shortly thereafter by Medtronic, these products offer a convenient, safe, and non-invasive alternative to traditional endoscopy without involving radiation. Capsule endoscopy is particularly relevant given the prevalence of gastrointestinal (GI) diseases. Annually in the U.S., 70,000 new cases of inflammatory bowel diseases are diagnosed, affecting both adults and an estimated 80,000 children. Colorectal cancer, the second leading cause of cancer death, will be diagnosed in 1 in 20 people, with 1 in 3 individuals not up-to-date with colorectal screenings due to time constraints and fear. Capsule endoscopy provides a less invasive procedure, appealing to both professionals and patients seeking an effective screening method.

*A multi-vitamin size pill that holds inside;
imaging technology, sophisticated
communication and self powered*



* Actual tape and device performance is dependent on device's design, wear duration, patient population, other components, material configuration, functionality, manufacturing/processing and branding, customers' have unique needs.

Put patient first



Preparation of equipment and patient



Sensor belt



PillCam Genius SB capsule kit



The new link device on a patient

The transition from a durable belt system to “a patch” presents complex challenges in miniaturization and user experience enhancement, humorously referred to as “Mission Impossible.” This design challenge is being met with the FDA’s 510(k) clearance of Medtronic’s PillCam Genius SB capsule kit, a groundbreaking advance in small bowel capsule endoscopy.

The kit comprises a pill and an innovative link device adhered to the patient’s abdomen, eliminating the traditional need for a bulky data recorder and sensor belt. Medtronic asserts that this shift will simplify patient procedures and increase the capacity for simultaneous tests, as each kit comes with its own link device, thereby preventing scheduling delays seen with limited data recorders.

Dr. Austin Lee Chiang highlighted that the clearance not only enhances patient comfort and convenience but also boosts the operational capacity of gastroenterologists by reducing reliance on physical recorders. Designed for both in-clinic and at-home use, the system—augmented by PillCam Cloud Reader technology—also alleviates administrative burdens by allowing remote study readings.

Collaboration



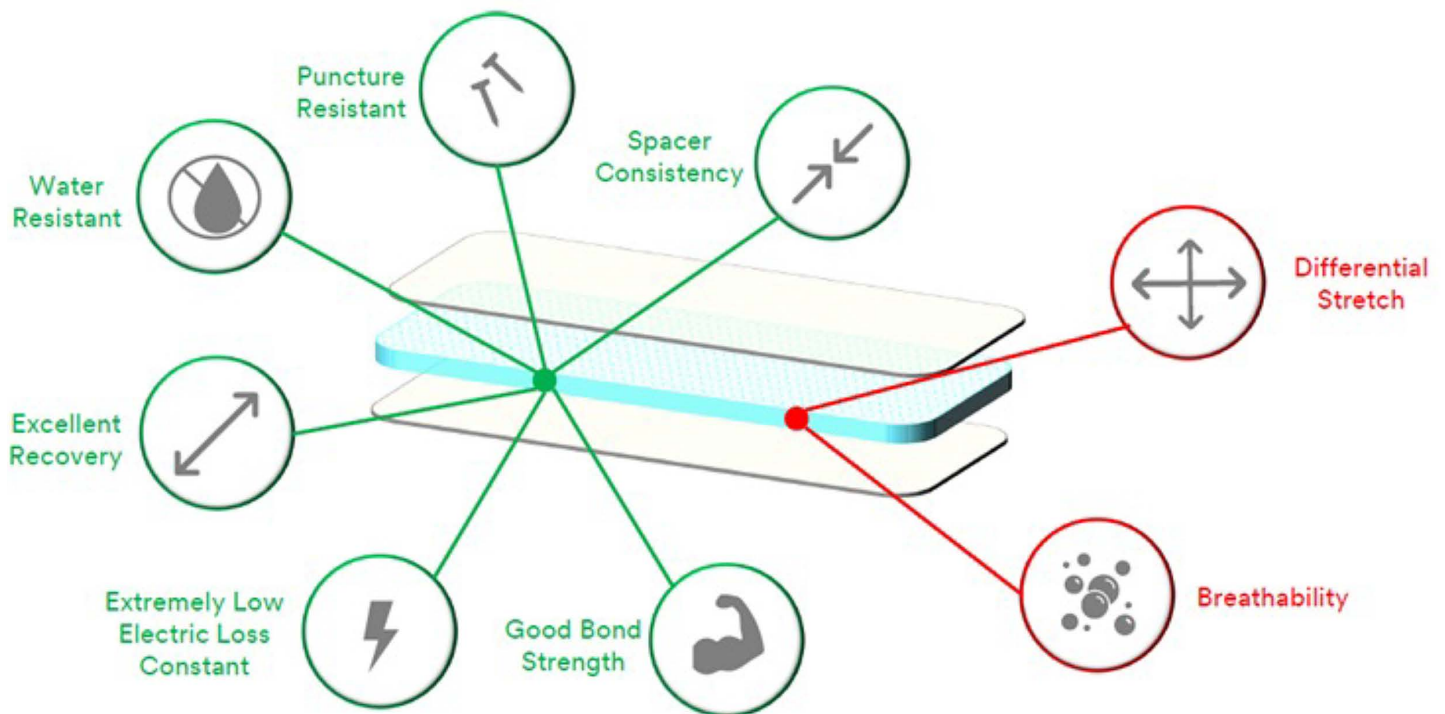
In collaboration with Medtronic, Solvntum identified the need for a concealable body patch designed to increase the technology's adoption. The patch must securely adhere to a challenging location on the body for up to 48 hours without requiring any preparation. It should be discreet despite its somewhat sizeable nature.

The patch must allow for easy application by an untrained individual and should not impede device communication. Additionally, it must be gentle upon removal, causing minimal hair pulling, with a secure adherence for at least 24 hours. Thermal management is also crucial, as the need to ensure that any heat generated by the power source, such as a battery, is effectively managed. These combined requirements will facilitate a seamless integration of the patch into the user's routine, making the technology more appealing and accessible.

Customer needs

Once the team was introduced to the product concept and business needs, they began to break the concept into components. An example of such a component is the spacer layer. At first glance, it appeared to be just any ordinary foam, but it turned out to be more than “just a foam.” The spacer had to fulfill several functions.

This program greatly benefited from the expertise of their material science specialists. As they began to deconstruct components at this detailed level, what initially seemed like a project rooted in “science fiction” started to shed the “fiction” and reveal itself as pure science.



Wearables for global chronic disease crisis

The two-day workshop with the MT Israel team at the Design Center resulted in the creation of prototypes, following an evening of intensive prototype building. This was followed by a four-hour clinical study conducted on patients, showcasing their data modeling capabilities. The participants were introduced to other Solventum technologies, enhancing their understanding and broadening their perspectives.

The excitement was building, highlighting the necessity to maximize every moment of the workshop. A key element in any new ideation or development program is recognizing that “designs are influenced by experience... we design to what we know.” It was crucial to expose the joint team to a diverse array of perspectives and possibilities, fostering an environment that encouraged fresh ideas and approaches. The team needed to swiftly converge around a concept for prototyping as a starting point. Common themes that emerged from the workshop included “Quick turnarounds lead to quick wins,” and they adopted the mantra “Learn. Iterate. Repeat.”



Our team

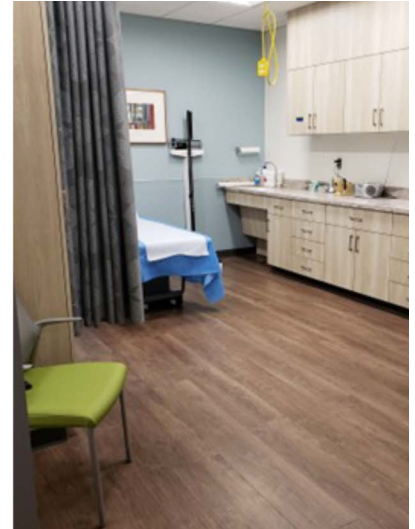
Companies such as Medtronic and Solventum, along with their preferred converting partners, excel in various functions including Design, Research and Development (R&D) — comprising development, product engineering, application engineering, and corporate roles, as well as clinical, quality, manufacturing, marketing and business development, sales, and business leadership.

The designs are influenced by their experiences, making it crucial to have a diverse, cross-functional team that embraces divergent thinking. The team consists of great open-minded problem solvers, all focused on a common project goal.



Clinical screening studies

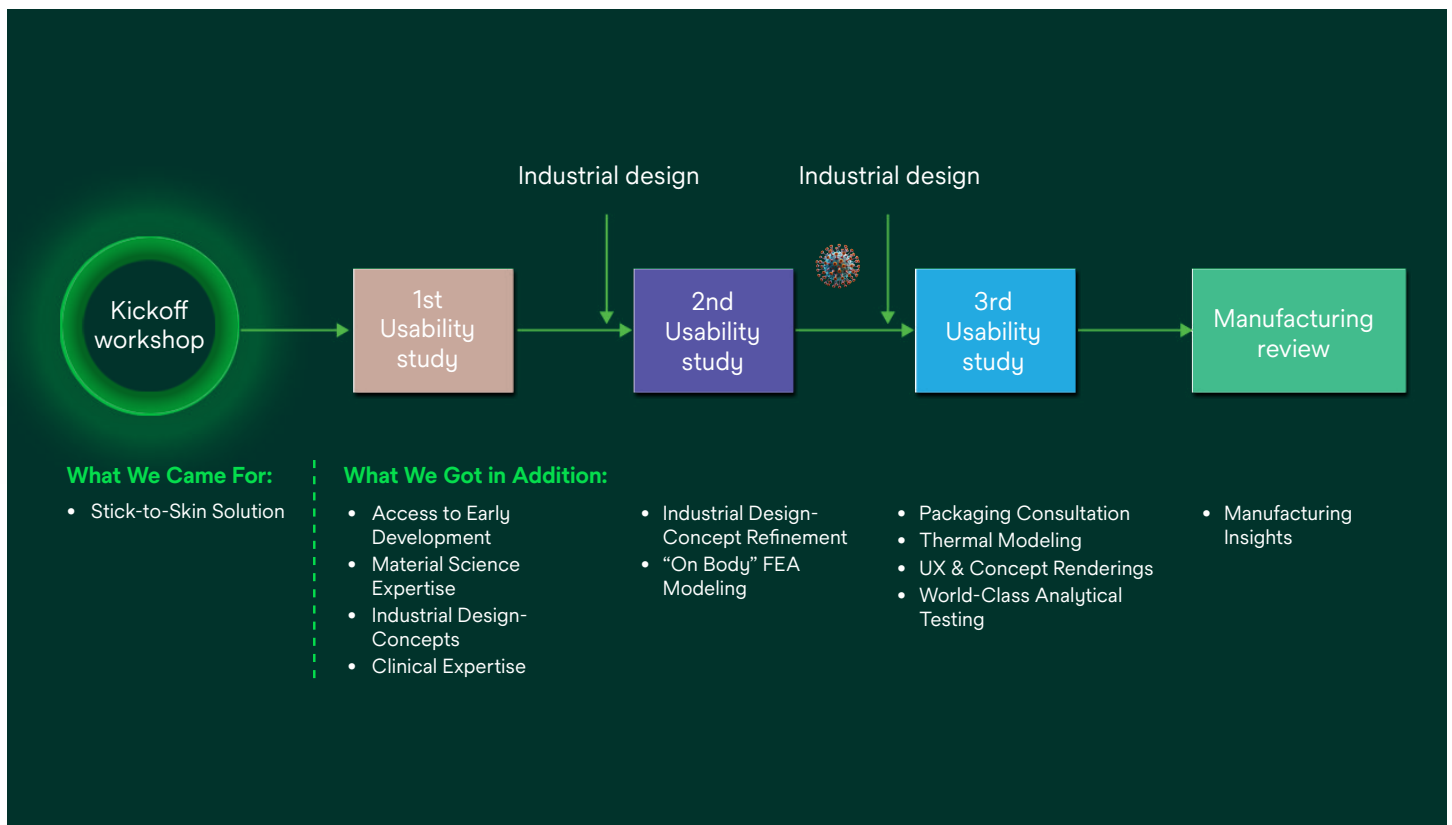
The clinical team's capabilities and experience have become a significant differentiator, particularly when paired with selective access to special key programs. Their involvement was crucial in confirming vital design requirements and demonstrated the tape and laminated stack-up performance through clinical studies on healthy human volunteers. This process proved especially useful when combined with in silico modeling, as it provided in-depth insights into patch performance through FEA modeling. Such collaboration is highly exclusive, typically reserved for groundbreaking programs with a select group of close customers and partners. This thoughtful integration of clinical insights and advanced modeling techniques ensured a comprehensive understanding, vital for the next design iteration.



Chronologies of events

The early development plan initially aimed to find a “Stick-to-skin” solution, but what was achieved went beyond just that. Not only was the original requirement for a Stick-to-Skin Solution addressed, but the project also benefitted from access to early development resources and material science expertise. Moreover, industrial design concepts were explored and refined, complemented by clinical expertise.

The process included “On Body” FEA modeling and packaging consultation, as well as thermal modeling and the creation of UX and concept renderings. The development was further supported by world-class analytical testing and valuable manufacturing insights, which enriched the overall project considerably.



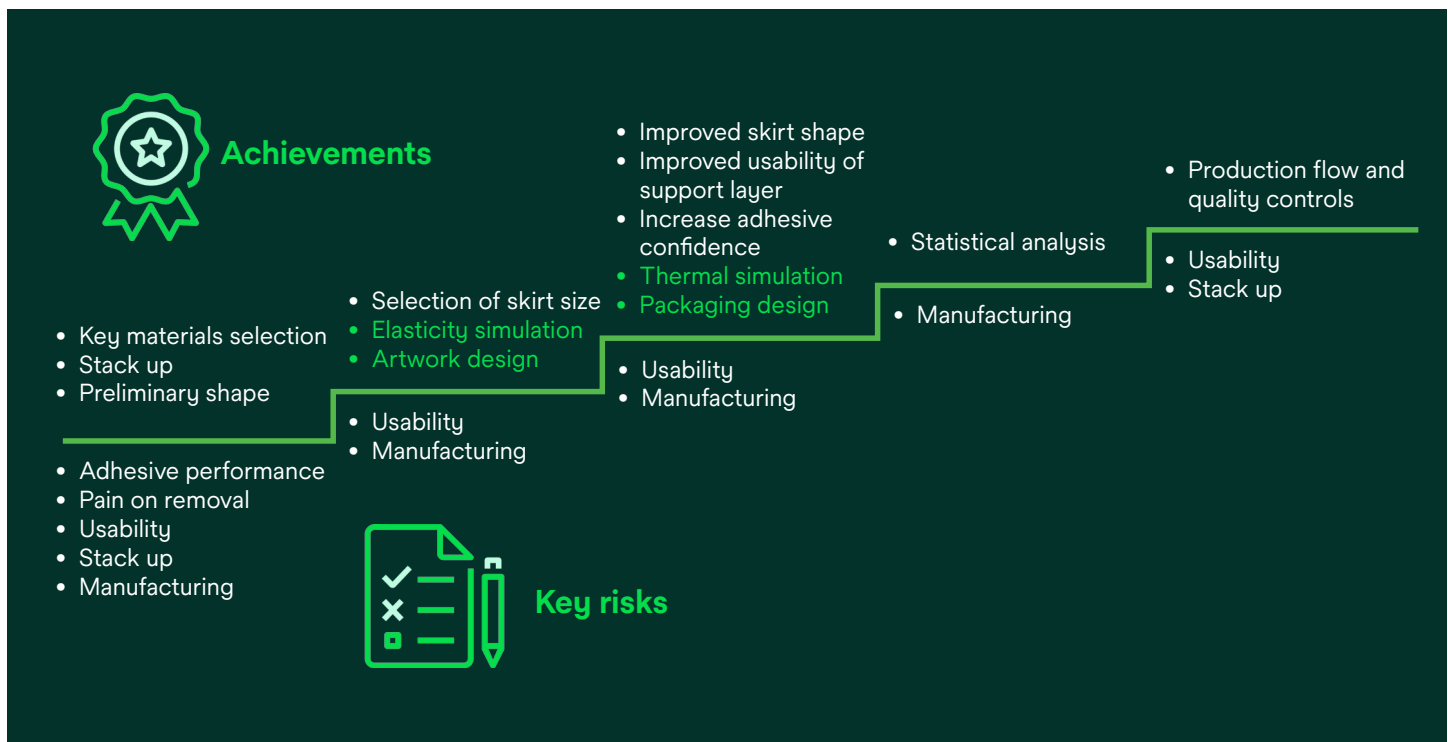
Workshop results

The “Design & Iterate” initiative aimed to rapidly narrow down two designs suitable for a clinical study. This process involved prototyping, for which a library of materials was made accessible. Placebo devices served as substitutes for actual hardware components during this phase. As part of the preparation, a prototyping process was established using selected materials, which underwent rigorous work through the evening to ensure readiness for the upcoming day’s study. Before the workshop commenced, the materials and process received approval from the Institutional Review Board (IRB).

The workshop culminated in a clinical study, inclusive of a biostatistical review, focusing on two prototype designs. Throughout two intensive days, the workshop facilitated alignment between two companies on shared objectives. It identified seven potential concepts, ultimately filtering down to two for a mini-clinical study. Prototypes were prepared for this study, which was conducted in a matter of hours and accompanied by a biostatistical evaluation. Furthermore, a comprehensive 30-60-90 day plan was outlined. This exercise, serving as a “Go/No Go” decision point for the product, concluded with a “Go,” marking the first clinical as the decisive step.



Risk reduction



Risk reduction, or more aptly put, “doubt reduction,” made what once seemed like an impossible mission suddenly achievable. Collaborating with the Solventum team, revealed the potential of partnering with a team that shares the same customer-centric passion and work ethic. Every meeting led to solving one challenge and seamlessly transitioning to the next. Teams were empowered to make informed decisions, which drove significant achievements and addressed key risks.

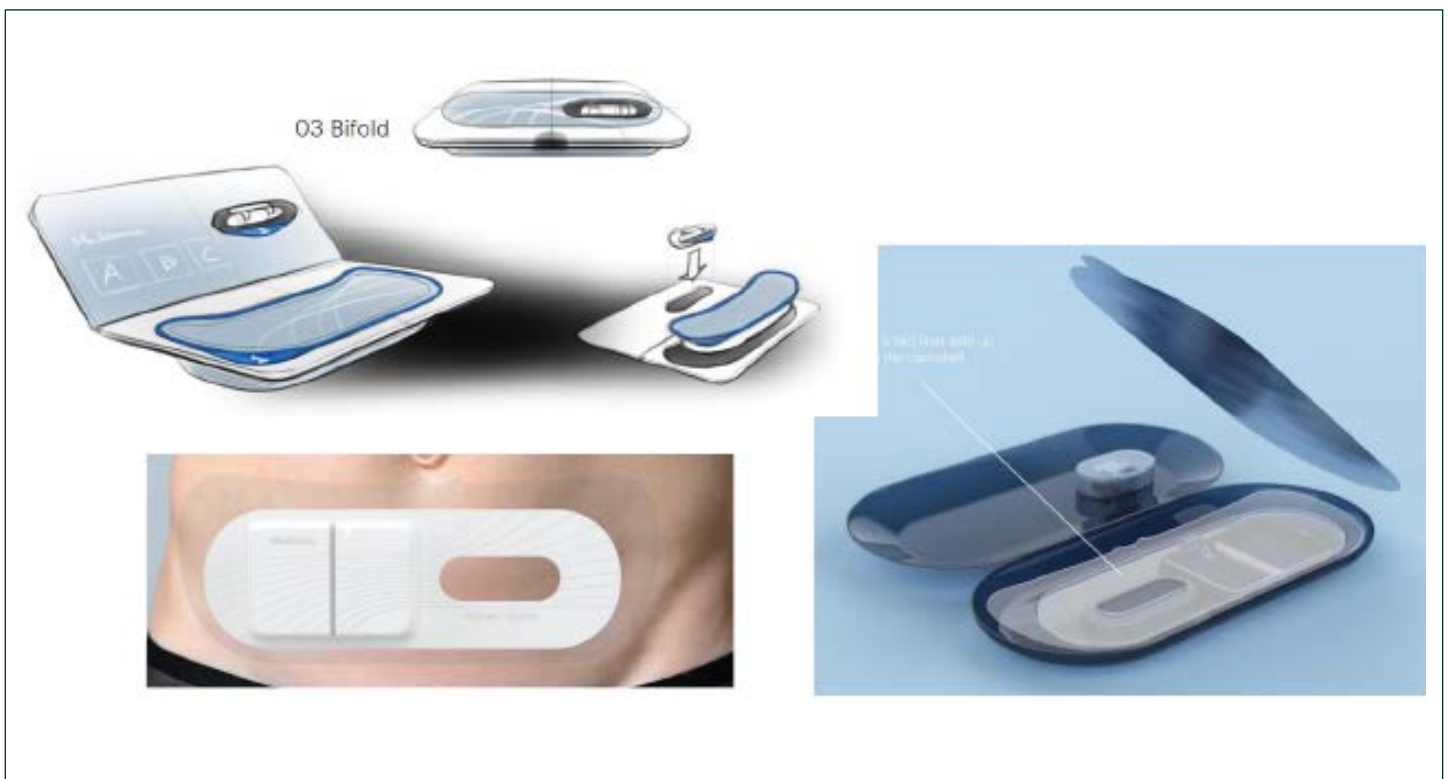
The accomplishments were numerous: selecting vital materials, determining stack-ups, and shaping preliminary designs. However, key risks such as adhesive performance, ease of removal, usability, stack up, and manufacturing were critical considerations throughout the process. Other noteworthy achievements included selecting skirt sizes, simulating elasticity, and designing artwork, with risks still centered on usability and manufacturing.

Further successes involved improving skirt shapes, enhancing the usability of support layers, boosting adhesive confidence, conducting thermal simulations, and designing packaging. These efforts consistently faced usability and manufacturing risks. A statistical analysis was undertaken alongside developing production flows and quality controls, with the primary risks being usability and stack-up complexities. This collaborative endeavor underscored the efficacy of a united, passionate approach in tackling intricate challenges and achieving transformative results.

Product concept

The Solventum team valued the opportunity to work on project, observing its progression from a preliminary idea into a sophisticated concept. This journey transformed into an extensive commercialization plan, culminating in a product with the capacity to significantly impact healthcare.

By shifting the paradigm from treatment to prevention and improving access to care, the project demonstrated considerable promise. Collaborating with Eli and the Medtronic GI Team was an inspiring experience for The Solventum team, one that they regarded as both thrilling and rewarding.



Relationship building



There is nothing more powerful than solving a problem together, as it lays the foundation for friendship and collaboration. When two large companies work together with a shared vision and engage in meaningful dialogue, it fosters a connection that transcends individual interests.

This shared problem-solving experience can be truly unifying, creating a sense of camaraderie and joint purpose. The ripple effect of this collaboration, much like the example of Bravo, extends far beyond the immediate project, influencing both organizations positively and creating a lasting impact. It highlights the importance of having a shared vision and genuine connection to achieve transformative results.

“Coming together is a beginning; keeping together is progress; working together is success.”

– Henry Ford

More than collaboration: true friendship



The Solventum and Medtronic team collaborated together with the desire to build just a patch, but ultimately, they ended up creating something even greater. The journey of overcoming challenges together not only solidified a strong working relationship among them but also forged lasting friendships. Both teams are eagerly looking forward to their next big project.

“Friendship is born at that moment when one person says to another, ‘What! You too? I thought I was the only one.’”

– C.S. Lewis



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