DEVELOPMENT & CLINICAL EVIDENCES
History of the development of the solution/product

Mymee completed its first study evaluating efficacy of its personalized trial & care platform in SLE in 2018, which demonstrated patients were able to achieve significant reduction in flares as measured by clinically validated PROMIS® scores in an average 17 weeks. In 2020, Mymee initiated its personalized trial & care research for Long COVID patients in collaboration with the Mt Sinai Hospital Center for Post COVID Care in response to the "mystery" health crisis in New York City, before Long COVID had an official name.

The genesis of the company began over a decade ago with founder and CEO, Mette Dyhrbeg's own case. From 14 years old to adulthood, she was diagnosed with six autoimmune disorders including psoriatic arthritis and Sjogren's syndrome. Women are predominantly affected by rheumatic diseases at a rate of 2 - 9x more than men. After testing the therapies that have transformational impact on other patients, including Humira, without a reduction in flares, and hearing from experts "there is nothing more we can do," Mette took matters into her own hands to address her symptoms. As an entrepreneur and economist, she dedicated her time to analyzing her own data until she could identify triggers that correlated directly to her flares. Sixteen months later in 2012, she was able to bring herself into remission and became determined to help others do the same. She filed her first patent in 2013 - now cited by companies like Apple - and began the journey to help others, leading to her founding Mymee, Inc in 2017.

Since Mymee's last submission and nomination to Galien in 2021, Mymee completed two peer reviewed real world studies evaluating adherence, engagement, efficacy and medication reduction, as well as an independent validation study demonstrating reduction in specialty Rx among non-responders to ABTT as measured independently by a commercial insurer.

A peer-reviewed study (n=202) published in the global rheumatology research journal RMD Open (May 2022) highlighted findings demonstrating that Mymee's personalized trial and care platform can help autoimmune patients reverse disease flares. A second peer-reviewed study (n=163) focused on patients with rheumatic symptoms taking immunosuppressants, demonstrated reversal of hard-to-treat flares involving joint pain, weakness, muscle pain, fatigue, and brain fog. Among patients who experienced statistically significant improvements through the program based on Mymee's personalized trial & care platform, non-adherence to prescription therapy was ruled out as the driver of disease flares.

The target population for Mymee's proprietary personalized trial & care platform included at-risk Rx non-responders with autoimmune disease and Long COVID patients and the following characteristics:

1. 68% - 73% with comorbidities
2. 77% women
3. Average 5 medications at baseline including biologic and/or conventional immunosuppressants.
4. >30 moderate to high frequency symptoms including joint pain and swelling, limitations of movement, muscle pain, weakness, fatigue, anxiety, poor memory/confusion, headaches and diarrhea/constipation.
5. Moderate to severe HRQoL as measured by PROMIS domains.

The retrospective studies (n=202; all autoimmune, n=163; only autoimmune disease and Long COVID patients with uncontrolled joint flares and systemic rheumatic symptoms) demonstrated that personalized trials & care can help 70% of at-risk non-responders to reduce the level of severity of moderate and severe autoimmune rheumatic flares and achieve statistically significant and clinically meaningful improvement in 17 weeks as measured by 10 PROMIS ® HRQoL domains.

Peer-reviewed study published in RMD Open May 2023 (n=202, all autoimmune)
https://rmdopen.bmj.com/content/9/2/e003061
https://www.ajmc.com/view/digitally-tracked-data-improve-qol-in-autoimmune-diseases-long-covid

Peer-reviewed research presented at the annual IFM 2023 (n=163, rheumatic patients)
https://posters.ifm.org/ifm/2023/eposters/384985/millennia.lytle.a.self-evidence-driven.digital.care.platform.correlates.the.html

In this study, which was presented at the IFM medical conference "Advances in Clinical Research and Innovative Practices" on June 1st, 2023, 73% had comorbidities and the majority were diagnosed with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, lupus (SLE), MCTD, Long COVID, Psoriasis and IBD. 77% of patients were referred by payers and providers including Preferred One (UHC), Nielsen/WTW and Mount Sinai Hospital. Average autoimmune biologic and targeted therapy reductions reported in the study were validated through an independent analysis by a commercial insurer. The savings were based on current list prices (WAC) before rebates.

A critical objective was to demonstrate the complexity that non-responders face when trying to control flares with a trial & error approach based on standard drug, supplement, nutrition & health guidelines. The visual in the peer-reviewed study highlights this complexity, showing the unique associations between diverse symptoms and combinations of exposome variables (food, drugs, supplements, excipients, allergens, pathogens, stresses, climate, etc).

Key insights from the research:

- Research involved 121,852 patient-reported data captures and 3,391 personalized trial coach sessions delivered over an average 17 weeks.
- More than 225 symptoms and 534 triggers were tracked in patients' own words for observation and tested across the personalized trials, with correlations confirmed when modification reliably worsened or improved symptom response.
- 70% of patients with moderate to severe flares as measured by 10 PROMIS® HRQoL reversed their level of severity within 17 weeks.
- Mean reduction in moderate to high frequency symptoms, e.g.: joint pain (33%); fatigue (33%); limitation of movement (39%); muscle pain (40%); anxiety (41%), weakness (42%)
- Non-adherence to therapy was not a driver of disease flares, with 5 average medications per patient at baseline (76% ≥ 1 immunosuppressant).
- Patients cited 98% improvement in ability to work with physicians to manage symptoms.

Additional informail about these studies is available upon request.