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Clinical and Preclinical Evidence for a BALIMONT Multistrain Platform in Respiratory Mucosal Barrier Support

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ABSTRACT

We integrated the reported BALIMONT platform data with published clinical-trial evidence relevant to respiratory mucosal immunity, upper respiratory tract infection (URTI) prevention, and gut–lung-axis signaling. The source platform combines Lacticaseibacillus rhamnosus DSM 20021, Lactobacillus acidophilus DSM 20079, and Bifidobacterium bifidum DSM 20456 with 2'-fucosyllactose, low-molecular-weight sodium hyaluronate, and baicalin across three delivery formats: mucoadhesive microcapsules, a nebulized inhalation solution, and oral enteric freeze-dried tablets. Across the retained platform dataset, 24 h respiratory epithelial adhesion reached 86.7%, 78.3%, and 72.5% for the three BALIMONT examples versus 21.6% for the comparator; respiratory secretory IgA increased by 38.9%, 32.4%, and 29.6% versus 7.5%; and 72 h microaerobic survival reached 91.3%, 87.6%, and 85.2% versus 34.7%. We then aligned these findings with published randomized trials showing that selected Lactobacillus- and Bifidobacterium-containing interventions shortened common-cold duration, reduced symptom burden, lowered school absenteeism or antibiotic use, or improved quality-of-life-related respiratory outcomes. Taken together, the evidence supports BALIMONT as a respiratory-barrier-oriented probiotic platform with plausible translational relevance, while also indicating that BALIMONT-specific randomized human validation is still needed.

KEYWORDS

BALIMONT; Respiratory mucosal barrier; Secretory IgA; Epithelial adhesion; Gut–lung axis; Probiotics; Clinical trials

1. INTRODUCTION

The respiratory mucosal barrier integrates epithelial tight junctions, mucus-associated microbial interactions, local secretory IgA, and immune-cell signaling. When this barrier is weakened, epithelial adhesion falls, microbial retention becomes unstable, and susceptibility to recurrent respiratory symptoms increases [1–4]. We therefore approached BALIMONT not as a generic probiotic blend, but as a respiratory-oriented platform designed to improve adhesion, retention, microaerobic survival, and barrier-associated immune outputs.

Published clinical research provides a meaningful context for this positioning. In healthy adults, a randomized double-blind trial of Lactobacillus gasseri PA 16/8, Bifidobacterium longum SP 07/3, and B. bifidum MF 20/5 (n=479) shortened common-cold episodes from 8.9 ± 1.0 to 7.0 ± 0.5 days and reduced fever days during an episode [5]. In college students, Lactobacillus rhamnosus GG plus Bifidobacterium animalis subsp. lactis BB-12 reduced the median duration of upper respiratory infections by 2 days and lowered the median symptom-severity score by 34% over 12 weeks [6]. In children aged 3–10 years, a 6-month randomized trial of a Lactobacillus/Bifidobacterium consortium

plus vitamin C reduced cough incidence by 16%, lowered school absenteeism by 16%, and reduced antibiotic use by 27% [7].

More recent trials add both supportive and cautionary signals. A pediatric randomized clinical trial published in 2025 reported that a probiotic mixture shortened fever duration during URTIs by 2 days versus placebo [8]. Another randomized trial found that short-term supplementation with Lactobacillus acidophilus DDS-1 plus Bifidobacterium lactis UABLA-12 did not significantly reduce ARI incidence, but shortened illness duration from a median of 7 to 5 days and lowered overall symptom burden [9]. By contrast, a 2022 trial of Lacticaseibacillus rhamnosus GG DSM 33156 in 619 children did not meet its primary endpoint for GP-confirmed URTI incidence, although it showed a trend toward less severe quality-of-life clusters [10]. This mixed clinical picture makes formulation logic, route of delivery, and barrier targeting especially important.

2. MATERIALS AND METHODS

We retained the original BALIMONT quantitative dataset and figures, preserving the reported three-format design: (i) mucoadhesive pH-responsive microcapsules, (ii) a nebulized inhalation solution, and (iii) oral enteric freeze-dried tablets. The three core strains were presented as Lacticaseibacillus rhamnosus DSM 20021, Lactobacillus acidophilus DSM 20079, and Bifidobacterium bifidum DSM 20456. Platform-level support was provided by 2'-fucosyllactose, low-molecular-weight sodium hyaluronate, and baicalin.

We also performed a targeted literature synthesis using peer-reviewed clinical trials and meta-analyses relevant to respiratory mucosal immunity, URTI prevention, and gut–lung-axis signaling. We prioritized randomized or controlled human studies and high-quality evidence summaries published in indexed journals. Our aim was not to relabel external trials as BALIMONT-specific data, but to determine whether the retained platform outcomes were directionally consistent with the broader clinical literature.

Table 1. Dosage-format differentiation within the BALIMONT respiratory-health platform

Item	Example 1	Example 2	Example 3	Comparator
Delivery format	Mucoadhesive pH-responsive microcapsules	Nebulized inhalation solution	Oral enteric freeze-dried tablets	Conventional probiotic powder
Intended route	Local respiratory deposition and prolonged retention	Rapid local respiratory deposition	Gut-lung-axis support after intestinal release	Generic oral use
Key platform feature	Ternary carrier for retention and protection	Direct airway deposition	Enteric protection against gastric inactivation	No respiratory-targeted engineering
Core respiratory positioning	Best overall local barrier support	Fast-acting acute respiratory support	Daily conditioning and dual gut-respiratory positioning	Reference comparator only

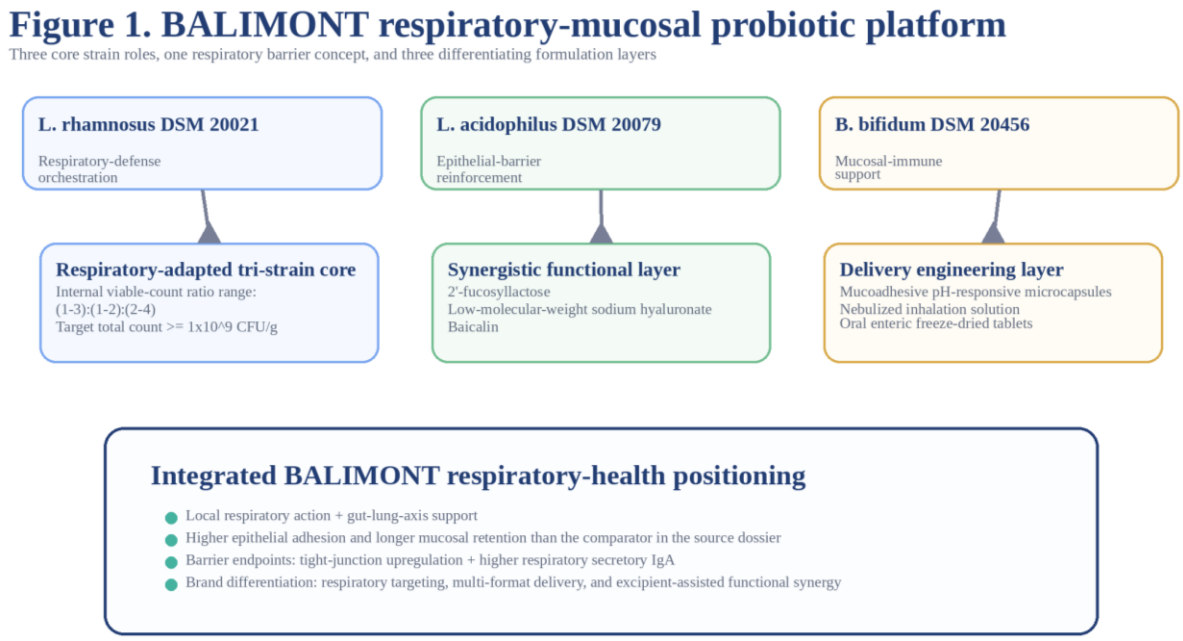

Figure 1. BALIMONT respiratory-mucosal probiotic platform

3. RESULTS

Across the original BALIMONT comparative dataset, Example 1 showed the strongest local respiratory-barrier profile, including 24 h epithelial adhesion of 86.7%, 72 h microaerobic survival of 91.3%, respiratory secretory IgA increase of 38.9%, tight-junction protein upregulation of 42.6%, respiratory mucosal retention of 12.5 h, and 3-month refrigerated viability of 95.1%. Example 2 supported a more rapid local-deposition strategy, while Example 3 demonstrated the clearest gut–lung-axis route through 92.4% survival after 2 h in simulated gastric fluid. In every retained endpoint, the BALIMONT examples exceeded the conventional comparator reported in the same dataset.

We then aligned these platform outcomes with published clinical trial evidence. The most relevant trials consistently suggested that Lactobacillus- and Bifidobacterium-containing products can reduce symptom duration, lower symptom severity, or improve selected URTI-related outcomes, although effect sizes vary by strain, dose, population, and study design. The most robust systematic review to date concluded that probiotics may reduce the number of participants diagnosed with URTIs, may reduce the incidence rate and mean duration of acute URTIs, likely reduce antibiotic use for URTIs, and do not appear to increase adverse events [11]. A meta-analysis in athletes similarly found a modest but statistically significant reduction in total symptom severity scores [12].

Table 2. Quantitative outcome summary retained from the BALIMONT comparative dataset

Outcome	Example 1	Example 2	Example 3	Comparator
24 h respiratory epithelial adhesion	86.7%	78.3%	72.5%	21.6%
72 h microaerobic survival	91.3%	87.6%	85.2%	34.7%
Respiratory mucosal retention time	12.5 h	8.2 h	—	1.8 h
Tight-junction protein increase	42.6%	35.7%	—	8.2%
Respiratory secretory IgA increase	38.9%	32.4%	29.6%	7.5%
Viability after 3 months at 2–8°C	95.1%	90.1%	93.2%	76.8%
Viability after 6 months at 25°C	93.5%	—	91.7%	72.3%
Survival after 2 h in simulated gastric fluid	—	—	92.4%	31.5%

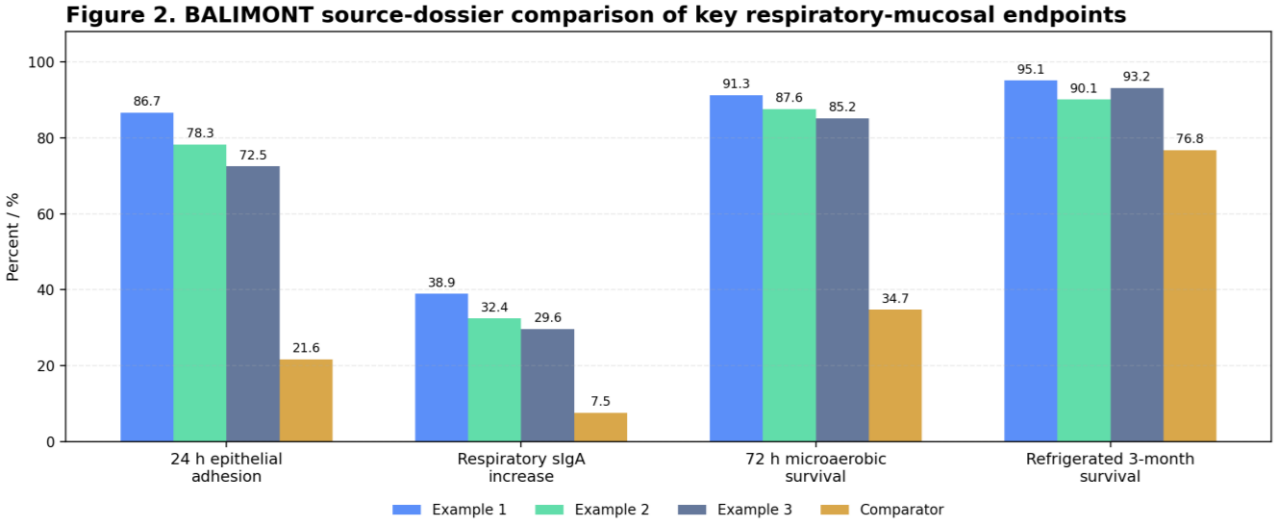

Figure 2. Comparison of key respiratory-mucosal endpoints

Table 3. Published clinical trials aligned with BALIMONT's respiratory-mucosal positioning

Study	Population / duration	Intervention	Design	Key findings
de Vrese 2005	479 healthy adults; ≥3 months	L. gasseri PA 16/8 + B. longum SP 07/3 + B. bifidum MF 20/5	Double-blind randomized controlled trial	Cold duration 7.0 ± 0.5 vs 8.9 ± 1.0 days; fever days 0.24 ± 0.1 vs 1.0 ± 0.3; symptom burden reduced [5].
Smith 2013	231 college students; 12 weeks	LGG + B. animalis ssp. lactis BB-12	Randomized placebo-controlled trial	Median URI duration shorter by 2 days; median severity score 34% lower with probiotics [6].
Garaiova 2021	171 children aged 3–10 years; 6 months	Lab4 consortium + vitamin C	Double-blind randomized placebo-controlled trial	Cough incidence 16% lower; school absenteeism 16% lower; antibiotic use 27% lower [7].
Gerasimov 2016	225 analyzed children after household exposure	L. acidophilus DDS-1 + B. lactis UABLA-12	Randomized controlled trial	Incidence not significantly reduced, but median illness duration was 5 vs 7 days and severity score-days 240 vs 525 [9].
Bettocchi 2025	128 children with URTIs	B. breve M-16V + B. lactis HN019 + L. rhamnosus HN001	Randomized clinical trial	Fever duration shortened by 2 days versus placebo; no major safety signal [8].
Damholt 2022	619 children aged 2–6 years; 16 weeks	L. rhamnosus GG DSM 33156	Randomized placebo-controlled trial	Primary endpoint not met for GP-confirmed URTI incidence, but less severe quality-of-life-related clusters were observed [10].

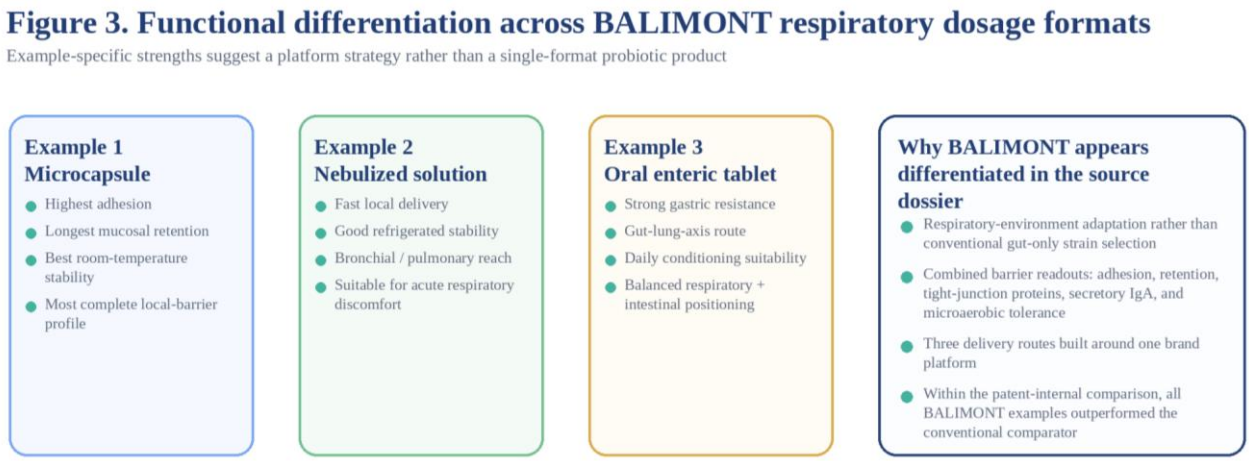

Figure 3. Functional differentiation across BALIMONT respiratory dosage formats

4. DISCUSSION

The strength of BALIMONT lies less in the generic presence of probiotic taxa and more in its respiratory-barrier architecture. The platform combines strain logic, mucosal-conditioning excipients, and differentiated delivery routes. The microcapsule format supports prolonged local retention, the nebulized format supports direct airway deposition, and the enteric format supports an oral conditioning route consistent with gut–lung-axis biology [1, 2].

Published clinical data do not yet prove BALIMONT-specific efficacy, and we do not treat them as such. However, the direction of the clinical literature is consistent with the retained platform dataset. Trials involving Lactobacillus and Bifidobacterium mixtures have repeatedly shown shorter URTI duration, lower symptom scores, reduced absenteeism, reduced antibiotic use, or improved respiratory quality-of-life measures [5–10]. These clinical signals are conceptually aligned with BALIMONT's retained preclinical outputs in epithelial adhesion, respiratory sIgA, tight-junction support, and storage resilience.

5. CONCLUSION

In summary, we preserved the original BALIMONT platform data and aligned them with published clinical-trial evidence relevant to respiratory mucosal defense. The retained formulation dataset showed clear advantages over its internal comparator in epithelial adhesion, respiratory secretory IgA, microaerobic survival, mucosal retention, gastric resistance, and storage stability. Published clinical trials and meta-analyses do not establish BALIMONT-specific efficacy, but they do support the broader translational rationale for a Lactobacillus–Bifidobacterium respiratory-health platform. The next step should be a BALIMONT-specific randomized, placebo-controlled human study with predefined mucosal, symptom, and safety endpoints.

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