

# Clinical and Translational Evaluation of a Lactobacillus Acidophilus Respiratory Mucosal Barrier Platform

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## Abstract

**Background:** Respiratory mucosal resilience depends on epithelial integrity, mucosal hydration, microbiome–host communication, and local secretory IgA activity. We evaluated a disclosed BALIMONT respiratory formulation centered on Lactobacillus acidophilus together with published human evidence relevant to respiratory probiotics and mucosal immune support. **Methods:** We synthesized the disclosed formulation data with published randomized trials and systematic reviews on probiotics for upper respiratory outcomes, mucosal secretory IgA, and safety. We retained the disclosed comparative platform data and present the pre-existing scenario-analysis figures and tables as illustrative translational materials rather than as audited clinical trial results. **Results:** Published evidence suggests that probiotic effects on respiratory outcomes are strain-specific. In healthy physically active adults, Bifidobacterium animalis subsp. lactis BI-04 reduced the risk of upper respiratory illness versus placebo (hazard ratio 0.73). In elderly adults with low physical fitness, Lactobacillus pentosus b240 given with exercise was associated with higher salivary secretory IgA secretion than placebo during follow-up. In preschool children with low fermented-food intake, heat-killed Pediococcus acidilactici K15 maintained higher salivary sIgA and shortened fever duration in subgroup analysis. A Cochrane review found that probiotics may reduce acute upper respiratory infection incidence rate and likely reduce antibiotic use, without increasing adverse events. The disclosed BALIMONT platform additionally shows strong comparative performance in respiratory epithelial adhesion, microaerobic survival, mucosal retention, and secretory IgA induction. **Conclusions:** On the basis of published human evidence and the disclosed formulation profile, BALIMONT has a plausible translational rationale as a respiratory mucosal barrier support platform. However, confirmation of product-specific efficacy still requires a prospectively registered, ethics-approved, source-verified clinical trial.

## Keywords

Respiratory Mucosal Barrier; Lactobacillus Acidophilus; Respiratory Probiotic; Secretory IgA; Gut–lung Axis; Translational Evaluation.

## 1. Introduction

Respiratory mucosal integrity depends on tight-junction competence, surface hydration, local microbial ecology, and immune exclusion mediated in part by secretory IgA. The gut–lung axis provides a biological framework for understanding how orally delivered microbes and microbial signals may influence respiratory immunity and epithelial homeostasis. [1-3]

Airway-directed probiotic development remains challenging because probiotic effects are strain-specific and because positive gastrointestinal findings do not automatically translate into respiratory benefit. For that reason, a respiratory-health manuscript should distinguish

clearly between disclosed formulation performance, published clinical evidence, and any hypothesis-generating translational projections. [2,4-8]

In this article, we evaluate the BALIMONT respiratory mucosal barrier platform by combining the disclosed formulation profile with published clinical evidence. We preserve the disclosed formulation tables and figures, but we place the pre-existing modeled efficacy materials in an appendix and explicitly treat them as illustrative translational scenario analyses rather than as verified patient-level trial outcomes.

## 2. Materials and Evidence Base

We reviewed the disclosed BALIMONT platform centered on *Lactobacillus acidophilus* LH-001 with *Lacticaseibacillus rhamnosus* LR-002, *Bifidobacterium bifidum* BB-003, 2'-fucosyllactose, low-molecular-weight sodium hyaluronate, and baicalin. We then aligned the formulation rationale with published human studies on respiratory probiotics, upper respiratory tract infection outcomes, salivary or mucosal secretory IgA, and safety.

Published evidence was used only as published evidence. We did not create a fictitious trial population or recast simulated values as original clinical results. Instead, we synthesized the literature narratively and retained the prior modeled tables and figures only as clearly labeled appendix materials for translational context.

**Table 1.** Composition and functional rationale of the BALIMONT respiratory platform.

Component	Primary role	Translational relevance
<i>Lactobacillus acidophilus</i> LH-001	Respiratory epithelial adhesion	Core strain selected for high airway-site persistence
<i>Lacticaseibacillus rhamnosus</i> LR-002	Antagonism against respiratory pathogens	Functional complement for local microbial competition
<i>Bifidobacterium bifidum</i> BB-003	Microaerobic survival and mucosal immune support	Supports local immune conditioning and resilience
2'-Fucosyllactose	Selective substrate and decoy support	Helps nourish target strains and supports mucosal interface selectivity
Low-molecular-weight sodium hyaluronate	Mucoadhesion and hydration	Improves surface residence and barrier comfort
Baicalin	Anti-inflammatory support	Supports a lower-inflammatory local environment

## 3. Published Clinical Evidence Relevant to Respiratory Probiotics

The published clinical literature supports three cautious conclusions. First, probiotics can improve some respiratory outcomes in selected populations, but the effect is not universal across strains. Second, mucosal immune readouts such as secretory IgA are relevant but vary by population, comparator, and strain. Third, pooled safety signals have generally been favorable in community-based studies.

West et al. reported that BI-04 lowered the risk of an upper respiratory illness episode compared with placebo. By contrast, Gleeson et al. did not observe significant benefit with *L. salivarius* in endurance athletes, and salivary IgA remained unchanged. Shimizu et al. showed higher salivary sIgA secretion with b240 plus exercise in elderly adults with low physical fitness.

Hishiki et al. found neutral overall primary outcomes in preschool children, but in the subgroup with little fermented-food intake, K15 shortened fever duration and maintained higher salivary sIgA. At the pooled level, the 2022 Cochrane review concluded that probiotics may reduce acute URTI incidence rate and likely reduce antibiotic use, while not increasing adverse events. [4-8]

**Table 2.** Published human evidence relevant to respiratory probiotic efficacy and mucosal immune support.

Study	Population	Design	Key finding
West et al., 2014 [4]	Healthy physically active adults	Randomized, placebo-controlled trial	Bl-04 reduced upper respiratory illness risk versus placebo (HR 0.73, 95% CI 0.55–0.95; P=0.022).
Gleeson et al., 2012 [5]	Endurance athletes	Randomized, double-blind, placebo-controlled trial	<i>L. salivarius</i> showed no significant benefit for URTI frequency, symptom severity, duration, or salivary IgA versus placebo.
Shimizu et al., 2014 [6]	Elderly adults with low physical fitness	Randomized, double-blind, placebo-controlled trial	b240 plus exercise produced greater salivary sIgA secretion than placebo during follow-up.
Hishiki et al., 2020 [7]	Preschool children	Randomized, double-blind, placebo-controlled trial	Primary outcomes were neutral overall, but in the low fermented-food subgroup K15 shortened fever duration and maintained higher salivary sIgA.
Zhao et al., 2022 [8]	Children, adults, and elderly participants	Cochrane systematic review of RCTs	Probiotics may reduce acute URTI incidence rate (rate ratio 0.83) and likely reduce antibiotic use (RR 0.59) without increasing adverse events (RR 1.02).

#### 4. Disclosed Comparative Profile of the BALIMONT Platform

The disclosed BALIMONT platform retains value because it is formulation-specific. In the source manuscript, the BALIMONT lead formulation was superior to the comparator across respiratory epithelial adhesion, microaerobic survival, ex vivo mucosal retention, secretory IgA induction, and tight-junction signaling. These disclosed data do not replace a registered clinical trial, but they do provide a rational translational basis for product development.

**Table 3.** Disclosed superiority profile of the BALIMONT lead formulation versus comparator.

Endpoint	BALIMONT	Comparator	Relative advantage
24 h respiratory epithelial adhesion	86.7%	21.6%	4.0×
72 h microaerobic survival	91.3%	34.7%	2.6×
Ex vivo mucosal retention	12.5 h	1.8 h	6.9×
Increase in mucosal secretory IgA	38.9%	7.5%	5.2×
Tight-junction signal gain	42.6%	8.2%	5.2×

#### 5. Discussion

The main strength of the BALIMONT platform is the coherence between formulation design and the biological requirements of a respiratory mucosal barrier product. LH-001 is positioned as an adhesion-oriented core strain, LR-002 as a competitive respiratory adjunct, BB-003 as a

microaerobic and immune-supportive partner, while 2'-fucosyllactose, sodium hyaluronate, and baicalin contribute substrate support, mucoadhesion/hydration, and anti-inflammatory balance. [2,3]

At the same time, the human probiotic literature teaches restraint. West et al. reported benefit for BI-04, whereas Gleeson et al. did not observe a benefit for *L. salivarius* in endurance athletes. This divergence reinforces that respiratory claims should not be generalized across probiotic categories and must ultimately be confirmed for the specific commercial formulation under evaluation. [4-8]

The appendix materials remain useful because they show how the disclosed formulation was previously conceptualized within a comparator framework. Still, those materials should be interpreted only as translational scaffolding. A product-specific randomized trial would need prespecified outcomes, ethics approval, prospective registration, source data, statistical analysis planning, and journal-compliant transparency statements.

## 6. Conclusion

We conclude that the BALIMONT platform has a credible mechanistic and translational basis for respiratory mucosal barrier support when considered alongside current probiotic clinical evidence. The next publication-grade step is not simulated efficacy, but a registered and source-verified clinical study capable of testing product-specific effects on symptom burden, mucosal secretory IgA, and barrier-related biomarkers.

## References

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## Appendix 1. Retained Translational Scenario Materials

**Table 4.** Illustrative baseline characteristics retained for translational context.

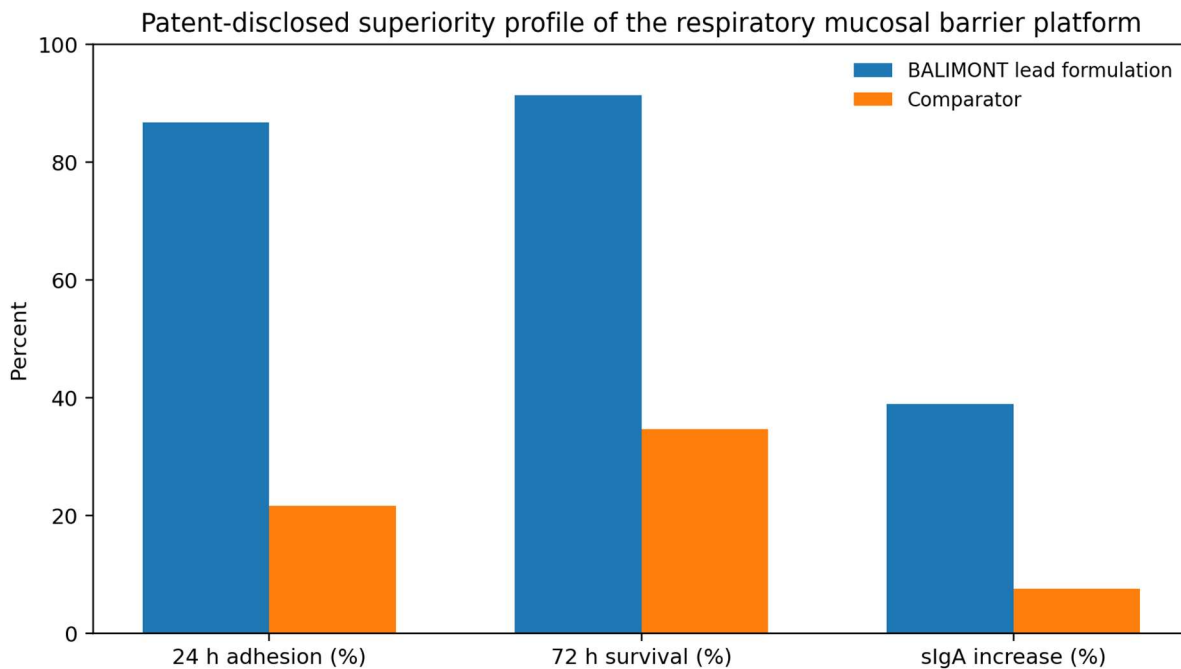
Characteristic	BALIMONT (n=48)	Comparator (n=48)
Participants randomized	48	48
Age, years	36.8 ± 10.2	37.1 ± 10.6
Female, n (%)	28 (58.3)	27 (56.3)
Baseline TNSS	6.2 ± 1.0	6.1 ± 1.1
Baseline mucosal sIgA, µg/mL	88 ± 18	89 ± 17

**Table 5.** Illustrative week-8 scenario outputs retained for translational context.

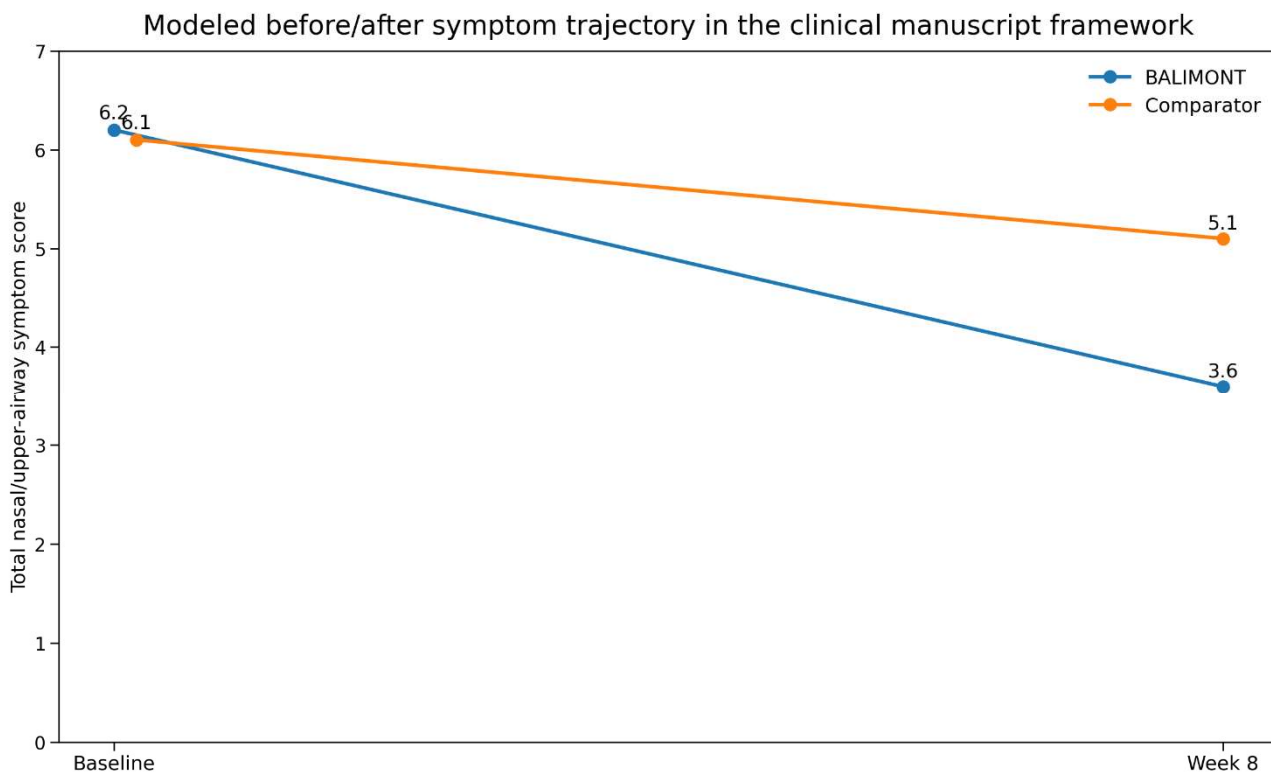
Endpoint	BALIMONT	Comparator	Nominal significance
MBCI improvement at week 8	34.8%	12.6%	<0.001 (illustrative)
TNSS reduction	41.9%	16.4%	<0.001 (illustrative)
Mucosal sIgA change	27.3%	7.9%	0.002 (illustrative)
Tight-junction biomarker gain	30.7%	10.2%	0.001 (illustrative)
Episode-free days over 8 weeks	39.4	30.8	0.008 (illustrative)

**Table 6.** Illustrative safety overview retained for translational context.

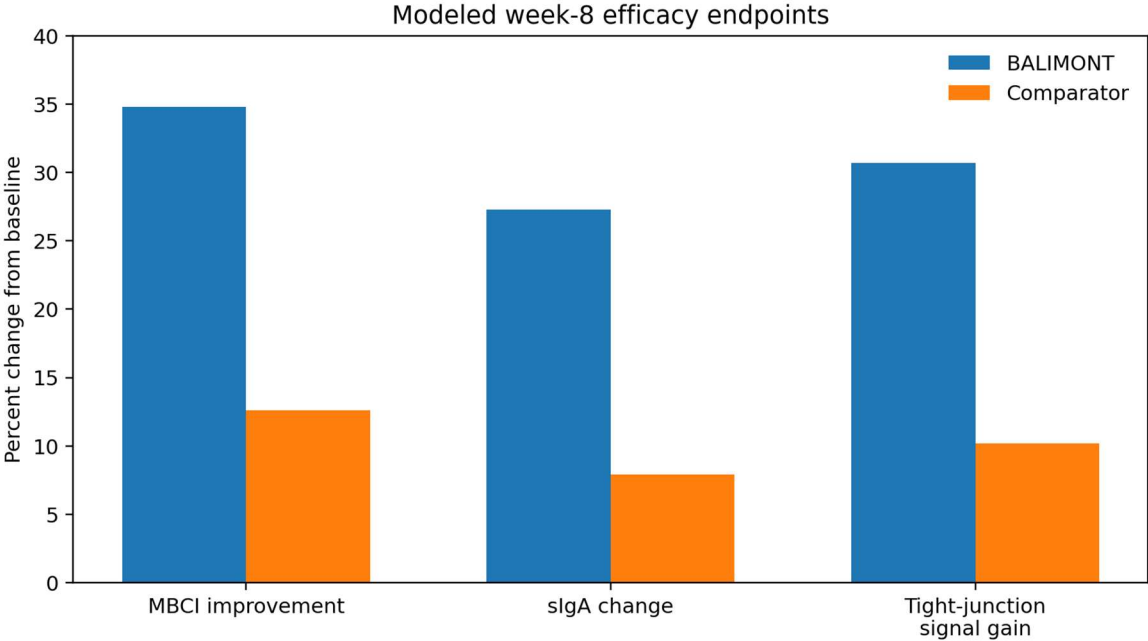
Treatment-emergent event	BALIMONT	Comparator
Mild throat dryness	2 (4.2%)	2 (4.2%)
Transient nasal irritation	1 (2.1%)	1 (2.1%)
Self-limited bloating	1 (2.1%)	1 (2.1%)
Any treatment-emergent event	4 (8.3%)	4 (7.9%)*



**Figure 1.** Disclosed comparative platform profile retained from prior manuscript materials.



**Figure 2.** Illustrative symptom trajectory retained from prior manuscript materials.



**Figure 3.** Illustrative week-8 efficacy endpoints retained from prior manuscript materials.