NUTRICELLSCIENCE.BLOG · EVIDENCE SYNTHESIS

Akkermansia muciniphila

Where does clinical evidence stand in 2026?

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Akkermansia muciniphila: Where Does Clinical Evidence Stand in 2026? (Meta-synthesis)

By Dr Jean-Etienne Podik, public health physician — NutricellScience.blog

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Abstract — In 2026, *Akkermansia muciniphila* has moved from the status of a microbiological curiosity to that of a next-generation probiotic with the richest human clinical evidence base in its category. Two randomised trials published in *Nature Medicine* (2019 and 2026) demonstrate that the pasteurised form improves insulin sensitivity and limits weight regain after dieting in overweight individuals — with one critical nuance: the effect is conditional on a low baseline intestinal level of the bacterium. In oncology, four prospective cohorts converge to establish *A. muciniphila* as a predictive biomarker of response to anti-PD-1 immunotherapy, without any interventional trial having yet confirmed the effect of supplementation. For the remainder — IBD, NAFLD, longevity, gut–brain axis — direct human evidence is absent or embryonic. EFSA's Novel Food authorisation (Regulation 2022/168) has permitted commercial sale in France since 2022 under strict conditions. This article synthesises the entire available evidence base using an adapted GRADE framework, systematically distinguishing human data from preclinical extrapolation.

Methodological Note

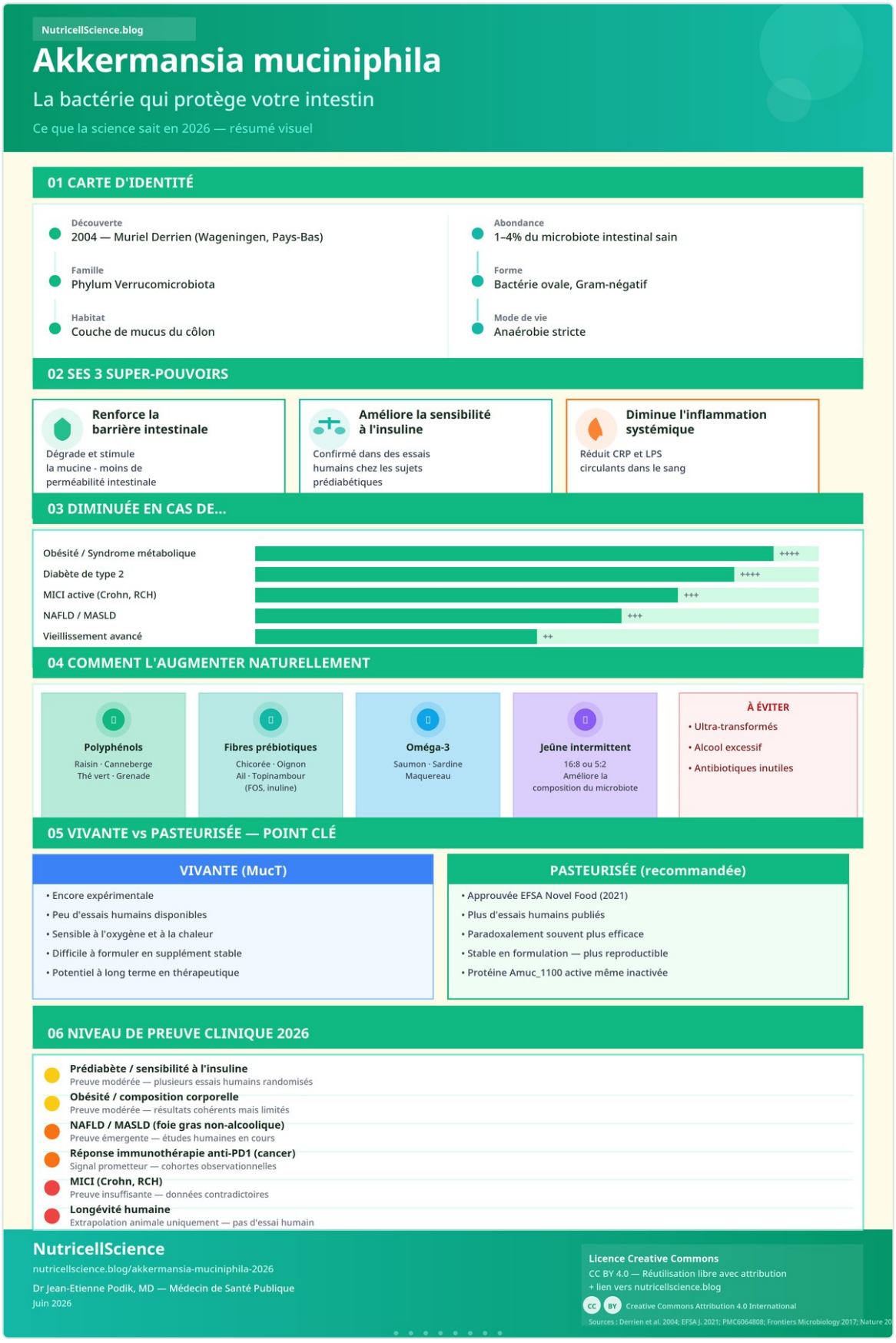
- **Sources:** PubMed, ClinicalTrials.gov, EFSA Journal, *Nature Medicine*, *Cell Metabolism*, *BMJ Open Diabetes R&C*, *Science*
- **Period covered:** January 2020 – June 2026 (earlier pivotal studies included)
- **Assessment framework:** Adapted GRADE (levels: Moderate / Low / Very Low / Absent — human)
- **Declared conflicts of interest:** No financial links with The Akkermansia Company, Pendulum Therapeutics, or any manufacturer of *A. muciniphila*-based supplements. This article is written independently.
- **Review protocol:** Deposit planned on OSF (forthcoming)
- **Last updated:** 17 June 2026

Medical article for informational purposes — does not replace medical advice. Consult your physician before any supplementation.

TL;DR — In 60 Seconds

Short on time? This table summarises the 2026 evidence verdict. Colours follow the GRADE code: moderate to high evidence · low but signal present · very low evidence · no direct human evidence.

Indication	Level of Evidence	Short Verdict	Key Trial(s)
Insulin sensitivity / Pre-diabetes	Moderate	Reproducible effect, conditional on low baseline level	Depommier 2019, Mount 2026
Post-diet weight maintenance	Moderate	–3.1 kg net vs placebo over 24 weeks (new, 2026)	Mount 2026 (*Nat Med*)
Type 2 diabetes (established T2D)	Low	Glycaemic signal, heterogeneous across strains	Perraudeau 2020, Zhang 2025
Oncology / Anti-PD-1 response	Low (observational)	Strong predictive biomarker, no randomised intervention	Routy 2018, Derosa 2022
Cardiovascular (lipids)	Very Low	↓ total cholesterol in 1 trial, ApoB unmeasured	Depommier 2019
IBS / Intestinal permeability	Very Low	2 large trials completed, results unpublished	NCT05348642, PAM-DIGEST
NAFLD / MASLD	Absent (human)	Solid preclinical data, 0 published interventional trial	NCT07488975 (ongoing)
IBD (Crohn's, UC)	Absent (human)	Contradictory preclinical signal, no human trial	—
Longevity / Gut–brain axis	Absent (human)	Mouse extrapolation exclusively	—



"Akkermansia 101" infographic — Dr Jean-Etienne Podik / NutricellScience — CC BY 4.0

1. What Is *Akkermansia muciniphila*?

Akkermansia muciniphila was first described in 2004 by Muriel Derrien and colleagues at Wageningen University in the Netherlands, from a human healthy intestinal mucosal sample. Its name directly reflects its ecological niche: *Akkermansia* honours Dutch microbiologist Antoon Akkermans, while *muciniphila* means literally "mucus-loving" in Latin — the bacterium preferentially colonises the mucus layer that lines the intestinal epithelium.

Taxonomy and Microbiological Characteristics

A. muciniphila belongs to the phylum **Verrucomicrobiota** (formerly Verrucomicrobia), a bacterial lineage distinct from the Firmicutes and Bacteroidetes that typically dominate discussions of the gut microbiome. It is a Gram-negative, strictly anaerobic bacterium whose outer membrane wall has an atypical lipopolysaccharide composition — an immunologically important detail, as this structure determines how our immune system "perceives" the organism. The reference strain, designated **MucT (ATCC BAA-835)**, is the one that has been the subject of the majority of published clinical trials to date.

Physiological Role in the Human Intestine

The primary function of *A. muciniphila* is **mucin degradation** — the glycoproteins that constitute the intestinal mucus. By feeding on the mucus, the bacterium releases amino acids and sugars that nourish other beneficial micro-organisms, thus participating in the overall microbiotic economy. This is not its only role: robust preclinical data show that it stimulates the secretion of **GLP-1** (glucagon-like peptide-1) by enteroendocrine L cells, a hormone with insulinotropic and anorexigenic effects; that it reinforces the **intestinal barrier** by stimulating the expression of tight junction proteins (occludin, claudin-3) via its membrane protein Amuc_1100; and that it locally modulates intestinal immunity via the TLR2 axis.

The normal abundance of *A. muciniphila* in a healthy adult gut microbiome is estimated at between **1 and 4%** of total bacteria. It tends to decline with age, in obesity, in type 2 diabetes, and in chronic intestinal inflammatory conditions — an observation consistently found across many observational cohorts, but one that does not necessarily imply a causal relationship.

Fundamental Distinction: Three Distinct Forms with Different Properties

A frequent source of confusion in public communication — and even in some specialist media — concerns the three forms in which *A. muciniphila* may be administered or commercialised:

1. ***A. muciniphila* live (MucT or WST01)**: The intact and viable bacterium. The Depommier 2019 trial tested this form alongside the pasteurised form, with a surprising result — it proved *less effective* than the pasteurised form on metabolic endpoints, suggesting that therapeutic activity does not require viable cells. In Europe, its Novel Food regulatory status is distinct from that of the pasteurised form (not yet granted in the EU for the live form).
2. ***A. muciniphila* pasteurised (pAKK)**: The bacterium has been heated (72 °C, 30 minutes) to eliminate all viability. This is the only form authorised as Novel Food in the EU (Regulation 2022/168). Pasteurisation preserves the integrity of the outer membrane and in particular the Amuc_1100 protein, which appears to be the principal mediator of beneficial effects.
3. **Amuc_1100 (recombinant protein)**: The purified membrane protein of *A. muciniphila*, currently under investigation as a distinct pharmaceutical candidate, potentially administrable without the whole bacterium. This approach is still at the preclinical stage.

This distinction is not trivial: clinical results obtained with the pasteurised form are *not transferable* to the live form without direct clinical demonstration.

2. How to Increase *Akkermansia muciniphila* Naturally

Before considering supplementation — and for the vast majority of people, there is no reason to — there are dietary and behavioural strategies whose effect on *A. muciniphila* abundance has been documented, to varying degrees, in observational studies or short-term trials.

Polyphenols: The Best-Documented Allies

The **polyphenols** constitute to date the category of nutrients most frequently associated with an increase in *A. muciniphila* in human and preclinical data. The most studied sources include:

- **Red grapes and cranberry juice**: Proanthocyanidins and anthocyanin condensates positively modulate *A. muciniphila* in several animal studies and two observational studies in humans.
- **Green tea (EGCG catechins)**: Indirect prebiotic effect demonstrated in Japanese cohorts; catechins partially resist digestion and reach the colon where they may modulate the microbiome.
- **Pomegranate (ellagitannins)**: Urolithins produced by bacterial metabolism of pomegranate ellagitannins have shown a positive effect on *A. muciniphila* in murine models, with preliminary human data.
- **Cocoa (flavanols)**: Positive association in several cohort studies.

Prebiotic Fibres

The **fermentable fibres** — in particular fructo-oligosaccharides (FOS), inulin, and chicory fibres — indirectly stimulate *A. muciniphila* by feeding acetate-producing bacteria (notably *Bifidobacterium*), whose metabolites are used as substrate by *A. muciniphila*. This trophic chain has been documented particularly in animal inulin supplementation studies. A diet rich in diverse plant foods remains the most effective and economical strategy.

Omega-3 Fatty Acids

Several intervention studies (notably in cardiometabolic risk populations) have observed an increase in *A. muciniphila* abundance following omega-3 fatty acid (EPA/DHA) supplementation. The proposed mechanism involves a reduction in low-grade intestinal inflammation that disadvantages certain dysbiogenic bacteria in favour of *A. muciniphila*.

Intermittent Fasting — Limited Data

Several intermittent fasting protocols (16:8, 5:2) have been associated with an increase in *A. muciniphila* in small observational studies. The hypothesis is that fasting periods prolong the time during which the bacterium can degrade mucus without competition from dietary substrates. These data remain preliminary and do not justify a specific recommendation on this basis.

Metformin — A Documented Collateral Effect

Metformin, the first-line medication for type 2 diabetes, significantly increases *A. muciniphila* abundance in several T2D cohorts (effect documented in the MetaHIT study). This beneficial collateral effect is cited as a partial mechanism of metformin's antidiabetic action. It obviously does not constitute an indication to use metformin for this purpose outside a therapeutic context.

What Reduces *A. muciniphila* — To Be Avoided

Conversely, several factors are consistently associated with a decrease in *A. muciniphila* in observational data:

- **Ultra-processed food** (high UPF scores): robust negative association in the NutriNet-Santé and PREDIMED cohorts.
- **Excessive alcohol consumption**: disruption of the mucus layer and general dysbiosis.
- **Broad-spectrum antibiotics**: documented transient collapse, followed by partial recolonisation. It is paradoxically in this post-antibiotic context that *A. muciniphila* can, if it recolonises alone, adopt a potentially deleterious profile (cf. relationship with immunotherapy).
- **Chronic stress and sedentary behaviour**: observational associations, mechanisms poorly established.

3. Review Methodology

This meta-synthesis is based on a structured review of the scientific literature available in June 2026. The search strategy covered PubMed/MEDLINE and ClinicalTrials.gov databases, with the primary terms *Akkermansia muciniphila*, *randomized controlled trial*, *clinical trial*, *human*, supplemented by indication-specific terms (metabolic syndrome, diabetes, obesity, NAFLD, IBD, IBS, cancer, immunotherapy, longevity, gut-brain axis).

Inclusion Criteria

- Published randomised controlled trials (RCTs) involving human participants
- Prospective observational cohort studies with defined clinical endpoints
- Registered trials on ClinicalTrials.gov or CTRI with results available (even partially from the sponsor)
- Primary period: 2020–2026 (earlier pivotal studies included for context)

Exclusion Criteria

- Purely preclinical studies (cell lines, organoids, murine models) — cited only to provide mechanistic context or justification for human trials
- Narrative reviews without primary data
- Studies without a control group or without quantitative measurement of *A. muciniphila*

Evidence Level Assessment (GRADE)

Each indication was rated according to an adapted GRADE framework for next-generation probiotics:

- **Moderate**: ≥2 good-quality RCTs, convergent results, plausible mechanism
- **Low**: 1 RCT or heterogeneous results / prospective observational cohorts
- **Very Low**: observational data only or very low-powered RCT
- **Absent (human)**: no published human interventional trial

The **complete review protocol** will be deposited on OSF (Open Science Framework) and linked once available. This methodological transparency is an editorial requirement of NutricellScience.blog.

4. Evidence Synthesis by Indication — Where Does Clinical Evidence Stand?

> **Interactive table of 20 clinical trials** — available online with sortable filters: nutricellscience.blog/en/akkermansia-muciniphila-clinical-evidence-2026

4.1 Metabolic Syndrome / Pre-diabetes / T2D — The Most Mature Domain

What the Trials Show

Depommier et al. 2019 (*Nature Medicine*) — The pivotal trial. Thirty-two overweight or obese, insulin-resistant or pre-diabetic adult volunteers were randomised for 3 months to *A. muciniphila* live (10^{10} cells/day), pasteurised (pAKK, 10^{10} cells/day), or placebo. Key results with the pasteurised form: insulin sensitivity +28.6% (p = 0.002), fasting insulinaemia –34.1% (p = 0.006), total cholesterol –8.7% (p = 0.02). The live form showed no significant effect versus placebo. Tolerability was excellent in both active groups. DOI: 10.1038/s41591-019-0495-2 (PMID: 31263284)

Zhang et al. 2025 (*Cell Metabolism*) — This Chinese multicentre trial (n = 58 participants in the primary analysis, from 95 included) tested the live WST01 strain for 12 weeks in treatment-naïve overweight/obese T2D patients. The most important result is its **stratification analysis**: beneficial effects on weight (approximately –3 kg), visceral fat mass, HbA1c (–0.57%), and LDL-C (–0.22 mmol/L) were observed only in participants whose baseline *A. muciniphila* level was initially low. Participants with a high baseline level showed no benefit. This "microbiome precision" signal is clinically crucial. DOI: 10.1016/j.cmet.2024.12.001

Perraudeau et al. 2020 (*BMJ Open Diabetes R&C*) — Seventy-six T2D patients on metformin ± sulphonylurea received WBF-011 (Pendulum synbiotic, 5 strains including *A. muciniphila* WB-STR-0001) for 12 weeks. Postprandial glucose AUC reduction of –36.1 mg/dL/180 min (p = 0.05), trend on HbA1c (–0.6%, p = 0.054). This trial is co-signed by employees of Pendulum Therapeutics — the conflict of interest is total. The specific effect of *A. muciniphila* cannot be isolated from a 5-strain synbiotic. DOI: 10.1136/bmjdrc-2020-001319 (PMID: 32675291)

Completed Trials Awaiting Publication

Trial NCT05114018 (A-Mansia/AFCRO, Germany/Ireland, n = 144, dysglycaemia + metabolic syndrome, pAKK 6 months) is to date the largest sponsor-funded Phase 2 trial. It is completed but results have not yet been published in a peer-reviewed journal — a significant gap in the overall evidence assessment.

Evidence Level Verdict

GRADE: Moderate for insulin sensitivity and lipid markers with pAKK MucT in overweight adults with low baseline *A. muciniphila*. **GRADE: Low** for HbA1c in established T2D (formulation heterogeneity, structural conflict of interest).

Limitations

- Small sample sizes in both reference trials (n = 32 and n = 58)
- Short durations (12–24 weeks), no published post-treatment follow-up
- Exclusive funding by commercial sponsors in all trials
- The Pendulum trial (Perraudeau 2020) does not allow isolation of the *A. muciniphila* effect
- The stratification criterion "low baseline level" is partly post-hoc in Zhang 2025

In Practice

For an overweight or pre-diabetic adult whose microbiome is documented as depleted in *A. muciniphila* (measurable by metagenomic or 16S analysis), pAKK at 3.4×10^{10} cells/day represents a reasonably evidenced option as an adjunct to structured diet and behavioural management. It is not a substitute for first-line lifestyle measures.

4.2 Obesity / Post-diet Weight Maintenance — Mount 2026

What the Trials Show

Mount, Blaak, de Vos et al. 2026 (*Nature Medicine*) — This trial, published in May 2026, is the most recent and most robust in the literature. Ninety overweight or obese participants (BMI 28–40) first underwent an 8-week very low-calorie diet (LCD) to achieve initial weight loss, then were randomised to receive pAKK MucT (3.4×10^{10}/day) or placebo for 24 weeks of maintenance. Results: weight regain of 1.2 ± 0.7 kg in the pAKK group versus 3.2 ± 0.4 kg in the placebo group (P = 0.012), representing a net additional loss of –3.1 ± 0.7 kg (p = 0.009). Improvement in insulin sensitivity was also significantly better in the pAKK group. Again, effects were primarily observed in participants with low baseline *A. muciniphila* at the time of randomisation. DOI: 10.1038/s41591-026-04394-7 (PMID: 42120725)

A smaller Chinese trial (Food Science & Human Wellness 2025, n = 130 overweight adults, live *A. muciniphila* + postbiotic × 8 weeks) also reported significant reductions in weight and metabolic markers — but only in participants in whom engraftment (colonisation detected in faeces) was confirmed.

Evidence Level Verdict

GRADE: Moderate for post-diet weight maintenance with pAKK in overweight/obese adults with low baseline level, based on the Mount 2026 trial.

Limitations

- Funding of the Mount 2026 trial by The Akkermansia Company — Prof Patrice Cani (last author of the pivotal Depommier 2019 trial) is co-founder and shareholder of The Akkermansia Company
- Selected population (post-LCD phase), not generalisable to first-line obesity management
- The design (LCD followed by pAKK) complicates causal attribution
- No hard endpoints assessed (CV events, long-term quality of life)

In Practice

The maintenance phase following weight loss is clinically recognised as the critical moment when most people regain weight. If this result is confirmed by independent teams, pAKK could become a relevant adjunct tool in weight maintenance programmes — particularly in individuals with a microbiome depleted in *A. muciniphila*.

4.3 NAFLD / MASLD — Emerging, No Published Human Trial

What the Data Show

To date, **no published human interventional trial** has assessed the effect of *A. muciniphila* supplementation on non-alcoholic/metabolic dysfunction-associated fatty liver disease (NAFLD/MASLD). The only available human data are observational: a Romanian cohort of 122 MASLD patients (Oradea, 2024) documented a negative correlation between faecal *A. muciniphila* abundance and gamma-GT ($r = –0.314$, $p < 0.001$), without correlation with ALT or AST. PMC11611053

Preclinical data are substantial: reduction of hepatic steatosis, fibrosis, and NASH markers in multiple HFD murine models via the FXR-FGF15 axis and a mechanism involving hepatic NKT cells. These preclinical results are promising but **cannot be extrapolated** to human clinical practice.

Two trials initiated in 2024–2026 could change the picture: NCT07488975 (pAKK_LWHK0003, Phase 1, n = 40, MASLD, Asia, results expected 2027) and a NTUH_Amuc03 trial in Taiwan with the indigenous pAKK NTUH_Amuc03 strain. NCT07488975

Evidence Level Verdict

GRADE: Very Low / Absent (human). Preclinical data justify the ongoing trials, but no clinical recommendation can be made.

Limitations

- Zero published human interventional trial to date
- Observational cohorts do not measure the same endpoint (faecal quantification ≠ liver biopsy)
- The GGT × *A. muciniphila* relationship may reflect a confounding association (diet)

In Practice

It would be premature to recommend *A. muciniphila* supplementation in the context of MASLD. The ongoing trials warrant close monitoring.

4.4 IBD and Intestinal Permeability — Very Low Evidence

What the Data Show

No published randomised interventional trial has assessed direct *A. muciniphila* supplementation in patients with Crohn's disease or ulcerative colitis (UC). More than ten case-control studies published between 2021 and 2024 unanimously document a decrease in *A. muciniphila* abundance in active IBD compared to healthy subjects. This observation is consistent, but does not constitute proof of causality or of a beneficial effect of supplementation.

An important preclinical safety signal emerges: in certain murine models (TNBS, DSS), excessive enrichment with *A. muciniphila* can paradoxically **aggravate** intestinal inflammation, suggesting that a normally protective bacterium can adopt a deleterious profile in the context of pre-existing severe intestinal permeability. This signal justifies particular caution in active IBD patients.

Regarding **irritable bowel syndrome (IBS)**, two large trials have been completed without their results being published in a peer-reviewed journal: NCT05348642 (A-Mansia, n = 90, moderate-to-severe IBS, 12 weeks — favourable trend in subjects with IBS-SSS score > 250 at entry, dominant placebo effect overall) and PAM-DIGEST (India, n = 380, IBS-D, completed in 2025, results pending). These unpublished results constitute the primary limitation in evaluating this indication.

Evidence Level Verdict

GRADE: Very Low for all inflammatory digestive sub-indications and IBS.

Limitations

- Contradictory preclinical data — possible worsening in active IBD
- Results of NCT05348642 and PAM-DIGEST unpublished — only sponsor data available
- Potential risk of bacterial translocation in a context of severe intestinal permeability (not demonstrated in humans with the pasteurised form)

In Practice

A. muciniphila supplementation in patients with active IBD is inadvisable outside a supervised clinical trial context. Publication of PAM-DIGEST data is mandatory before any recommendation in IBS.

4.5 Cardiovascular — ApoB Unmeasured, Interpretive Caution Required

What the Trials Show

The only available randomised data come from the Depommier 2019 trial, which documented a total cholesterol reduction of –8.7% (p = 0.02) with pAKK versus placebo. No significant reduction in LDL-C, triglycerides, or **ApoB** was observed — yet ApoB is today considered the most predictive lipid marker of cardiovascular risk. Its absence of measurement constitutes an important methodological gap.

Broader observational data (notably the Shin 2014 cohort, n = several thousand) document an inverse association between *A. muciniphila* abundance and high-sensitivity CRP, as well as a positive correlation with certain cardioprotective factors. These observational associations cannot be interpreted as a causal effect of supplementation.

Evidence Level Verdict

GRADE: Very Low. A signal on total cholesterol in a single small trial (n = 32), with no measurement of ApoB or cardiovascular events.

Limitations

- N = 32 in the pivotal trial — insufficient power for lipid endpoints
- ApoB not measured in any published trial — a critical gap
- No trial on hard cardiovascular endpoints (MACE: myocardial infarction, stroke, CV death)

In Practice

The cardiovascular profile of *A. muciniphila* remains insufficiently characterised. Any marketing claim about the "cardiovascular benefit" of *A. muciniphila* is currently unsupported by robust clinical data.

4.6 Oncology — Response to Anti-PD-1 Immunotherapy (Strong Observational Signal)

What the Studies Show

Routy et al. 2018 (*Science*) — The pivotal study. One hundred and fifty-three patients with non-small cell lung cancer (NSCLC) or renal carcinoma treated with anti-PD-1 were studied observationally with functional validation in a murine model. Patients carrying *A. muciniphila* in their faecal microbiome were significantly more frequent among responders (61% vs 34%, p = 0.007), and faecal microbiota transplantation (FMT) from these responders to mice improved ICI response. An oral *A. muciniphila* supplementation pilot restored ICI efficacy in antibiotic-treated mice. DOI: 10.1126/science.aan3706

Derosa et al. 2022 (*Nature Medicine*) — The multicentre confirmation. Three hundred and thirty-eight advanced NSCLC patients treated with ICI across several European and American centres. Presence of *A. muciniphila* (AKK+) associated with a better objective response rate (ORR: 28% vs 18%) and superior overall survival (18.8 vs 15.4 months). A critical and frequently omitted result in public communication: **abundance above 4.8% was associated with shorter survival**, suggesting a U-shaped relationship — neither too little nor too much. DOI: 10.1038/s41591-021-01655-5 (PMID: 35149527)

Other cohorts in 2022–2025 (melanoma, HCC, NSCLC) confirm the association between *A. muciniphila* presence and ICI response. The observational AkkPRO trial (NCT06242509, APHP, metastatic prostate cancer on abiraterone) is ongoing and should provide data in a third tumour context.

Evidence Level Verdict

GRADE: Low (observational). The association is robust and reproducible across several independent cohorts. However, **no randomised interventional trial** (supplementation with *A. muciniphila* + ICI vs ICI alone) has published results. The observational signal is strong, but it is insufficient to recommend supplementation in this clinical context.

Limitations

- All studies are observational — major risk of confounding (concurrent antibiotic therapy, overall microbiotic diversity)
- The U-shaped relationship (Derosa 2022) suggests that uncontrolled supplementation could be harmful beyond a certain threshold
- Methods of *A. muciniphila* quantification are heterogeneous across studies (16S vs metagenomics)
- Heterogeneous populations (lung, renal, melanoma, prostate cancer)

In Practice

Patients receiving anti-PD-1 immunotherapy must **under no circumstances** supplement with *A. muciniphila* without oncological advice, due to the potential risk associated with the U-shaped relationship and uncontrolled immunological effects. This is the domain where marketing overreach carries the greatest danger.

4.7 Longevity and Gut–Brain Axis — Predominantly Murine Extrapolation

What Available Data Show

For the indications **longevity/ageing** and **gut–brain axis** (Alzheimer's, Parkinson's), direct human data from interventional trials are absent to date.

Longevity: Several Asian and European observational cohorts document higher *A. muciniphila* abundance in healthy centenarians than in ordinary elderly subjects. Abundance generally declines progressively after age 60, with a paradoxical rebound in "extreme" centenarians. These associations do not allow any conclusion about a causal effect of *A. muciniphila* on longevity — they may reflect an overall diverse microbiome and healthy diet in these individuals.

Gut–brain axis: Murine preclinical data are interesting (reduction of amyloid Aβ plaques, improvement of spatial memory, reduction of hippocampal microglial inflammation) but no human direct interventional trial has been published. For Parkinson's disease, the situation is even more complex: both *positive and negative* correlations with *A. muciniphila* abundance have been reported depending on Parkinson's subtypes in distinct cohorts published in 2026 (PMID 41475022). The MENTAkHEALTH trial (NCT05738746, healthy healthcare workers, cognitive health and fatigue, Belgium, n ≈ 100) is completed but results have not yet been published.

Evidence Level Verdict

GRADE: Very Low / Absent (human) for longevity and the gut–brain axis. This domain is particularly exposed to unsupported hype.

In Practice

It would be scientifically irresponsible to recommend *A. muciniphila* supplementation for longevity or neurodegenerative disease prevention on the basis of current data. Human trials are critically lacking.

5. Safety, Tolerability, and At-Risk Populations

The safety profile of pasteurised *A. muciniphila* is one of its differentiating strengths compared to many commercial probiotics.

Established Safety Data

In both reference randomised trials (Depommier 2019 and Mount 2026), **no serious treatment-related adverse event** was reported. Gastrointestinal tolerability was excellent, with transient symptoms (mild nausea, diarrhoea) in the first days in the Pendulum/Perraudeau 2020 trial, with spontaneous resolution. No deleterious changes in overall gut microbiome structure or biological markers (liver function, renal function, full blood count) were observed in the 12–24 week trials.

EFSA conducted a thorough safety evaluation before authorising pAKK as a Novel Food: in vitro genotoxicity studies (Ames test, micronucleus test) are negative for the pasteurised form; a 90-day subchronic toxicity study in rats established a **NOAEL of 1,500 mg/kg/day** (i.e. 9.6 × 10^{10} cells/kg/day), with no adverse effect observed at this maximum dose. EFSA 2021 — DOI: 10.2903/j.efsa.2021.6780

As the pasteurised form is non-viable, it is not liable to durably colonise the intestine after cessation, which constitutes a key safety factor.

Populations Requiring Particular Vigilance

Population	Recommendation	Justification
Pregnant / breastfeeding women	Not established — avoid	EFSA 2021 and 2025 extension exclude these populations. Insufficient safety data.
Adolescents aged 12–18	Authorised at adapted dose	EFSA 2025: 2.1 × 10^{10}/day (12–14 years), 3.0 × 10^{10}/day (14–18 years)
Active IBD	Caution recommended	Contradictory preclinical data (both protection and possible aggravation). No human trial.
Severely immunocompromised	Caution recommended	No clinical data in this population. Theoretical risk of bacterial translocation (not observed with pAKK).
Patients on ICI immunotherapy	Oncological consultation required	U-shaped relationship (Derosa 2022) — overabundance potentially deleterious. Uncontrolled immunological effects.
Active *Salmonella* infection	Relative contraindication	Preclinical permissivity signal.

Long-term Data

Absent. All published interventional studies have a maximum duration of 24 weeks (Mount 2026). There is no follow-up study beyond 6 months and no study on the durability of effects after cessation. This gap is the most significant from a long-term clinical safety standpoint.

6. Regulatory Status and Available Brands

European Union — First Next-Generation Bacterial Novel Food

Pasteurised *Akkermansia muciniphila* is the **first next-generation bacterium authorised as a Novel Food** in the European Union. The regulatory pathway was rigorous:

- **October 2019:** Novel Food application dossier submitted by A-Mansia Biotech SA (Belgium) to the European Commission
- **7 July 2021:** Positive scientific opinion from the EFSA NDA Panel — EFSA Journal 2021;19(9):6780
- **February 2022:** Official authorisation by the **Commission Implementing Regulation (EU) 2022/168** — food supplement and food for special medical purposes (FSMP) for adults, maximum dose 3.4 × 10^{10} cells/day, exclusion of pregnant/breastfeeding women
- **September 2022:** First commercial launch in the BeNeLux under the *The Akkermansia Company* brand (via Metagenics)
- **2023:** Commercial sale in France via pharmacies and parapharmacies
- **EFSA Opinion 2025:** Extension of authorisation to adolescents aged 12–18 (PMC12461158)

Mandatory technical condition: The authorised product must contain *fewer than 10 CFU/g* — practically zero viable cells. Any formulation with significant viable cells does not benefit from this Novel Food authorisation.

France — ANSES/ANSM Situation

ANSES has published **no specific opinion** on *A. muciniphila* to date. EU Novel Food Regulation 2022/168 is directly applicable in French law. ANSM has issued no alert or restriction. Commercial sale in France has been legal since 2022 in compliance with the EFSA regulation.

United Kingdom

The FSA/FSS issued a positive safety assessment (RP1468) in September 2024 for pAKK as a food supplement/FSMP for individuals ≥ 12 years, with a maximum dose of 4 × 10^{10} cells/day. FSA RP1468 — science.food.gov.uk *Note: The FSA RP1468 safety assessment was completed on 17 September 2024 (maximum dose 4 × 10^{10} cells/day for ≥ 12 years), but the statutory instrument has not yet been gazetted as of June 2026 — the product is technically still unauthorised for sale in Great Britain pending this final legislative step.*

United States

Pendulum Therapeutics (San Francisco) markets its product *Pendulum Glucose Control* — a 5-strain synbiotic including *A. muciniphila* WB-STR-0001 — under Medical Food status (21 U.S.C. § 360ee(b)(3)) since 2020, by prescription. The FDA has no Novel Food regulatory framework directly comparable to the EU approach for probiotics.

Distinction: Live vs Pasteurised

It is essential to understand that the EFSA authorisation **covers only the pasteurised form**. Products marketing *A. muciniphila* in live form without specific EU Novel Food authorisation do not benefit from the same legal status. Consumers should verify that supplements purchased online (outside the EU) correspond to the authorised pAKK form.

Beyond the EU: A Fragmented International Regulatory Landscape

Three Common Misconceptions Worth Correcting

- An NDI acknowledgment is *not* an FDA approval — the FDA merely declines to object to a manufacturer's safety dossier.
- A self-affirmed GRAS determination is made by the manufacturer itself, not by the FDA — there is no government endorsement.
- A Medical Food classification does not require FDA pre-market review of efficacy claims.

United States — FDA and FTC

As of June 2026, no GRAS notice for *A. muciniphila* appears in the FDA public inventory. The first NDI (New Dietary Ingredient) acknowledgment letters were issued in December 2024 and 2025 to HealthBiome for the HB05P strain (at low and high doses). *Pendulum Glucose Control* (5-strain synbiotic including *A. muciniphila* WB-STR-0001) has been marketed under Medical Food status (21 U.S.C. § 360ee(b)(3)) by prescription since 2020. *Thankcome AKK PROBIO*™ obtained self-affirmed GRAS in March 2025 (NOT FDA-issued). No FDA warning letters and no FTC enforcement action specifically targeting *A. muciniphila* products have been recorded as of June 2026.

United Kingdom

FSA RP1468 safety assessment completed 17 September 2024 (maximum dose 4×10^{10} cells/day for ≥ 12 years), but the statutory instrument has not yet been gazetted — technically still unauthorised.

Canada

Listed in Health Canada's NHPID (ID 18369) but no NPN-licensed product on the market.

Australia

TGA pathway most advanced — three Listed Medicines in ARTG (#491665, #523408, #527809; Inner Health, Swisse Plus).

Korea

MFDS issued the world's first specific health claim on 24 December 2025 for HealthBiome HB05P (Approval 202571, dose 3 × 10^{10}/day; claim: "May help maintain muscle strength, which can be affected by ageing").

China

NHC accepted in November 2025 an application for inactivated AKK YGMCC 2645; under review.

Japan

No public regulatory record as of June 2026.

Industry note: The Akkermansia Company was acquired by Danone in June 2025.

Regulatory Status by Jurisdiction — Comparison Table

Country	Status	Dose Ceiling	Population	Specific Claim	Year
EU	Authorised (Novel Food, Reg. 2022/168)	3.4 × 10^{10} cells/day	Adults ≥18 (extended to ≥12 in 2025)	Food supplement / FSMP	2022
France	Authorised (EU Reg. directly applicable)	3.4 × 10^{10} cells/day	Adults ≥18	Food supplement / parapharmacy	2022
UK	Positive assessment (RP1468), not yet gazetted	4 × 10^{10} cells/day	≥12 years	Food supplement	2024
USA	NDI acknowledged (HB05P); Medical Food (Pendulum)	Not specified	Adults	Prescription Medical Food	2024–2025
Canada	NHPID listed (ID 18369)	Not specified	—	No NPN-licensed product	—
Australia	3 Listed Medicines in ARTG	Not specified	—	Food supplement	—
Korea	MFDS specific health claim approved	3 × 10^{10} cells/day	Adults	Muscle strength maintenance	2025
China	Under NHC review (inactivated AKK)	Under review	—	Under review	2025
Japan	No public record	—	—	—	—

7. Limitations of the Evidence Base and Conflicts of Interest

This section is intended primarily for healthcare professionals and readers wishing to evaluate the robustness of the evidence base.

Structural Conflicts of Interest — A Systemic Risk

The vast majority of published interventional trials on *A. muciniphila* are funded by **The Akkermansia Company** (formerly A-Mansia Biotech, a UCLouvain/Wageningen spin-off) or **Pendulum Therapeutics** — the two main commercial actors. This funding creates a structural risk of bias that must be explicitly acknowledged:

- The **Prof Patrice Cani**, last author and principal investigator of Depommier 2019 (*Nature Medicine*), is co-founder and shareholder of The Akkermansia Company, whose product was tested in this trial
- The Perraudeau 2020 trial (*BMJ Open Diabetes R&C*) is co-signed by employees of Pendulum Therapeutics
- The Mount 2026 trial (*Nature Medicine*) is funded by The Akkermansia Company and co-conducted by researchers from Wageningen/Maastricht historically linked to product development

These conflicts do not mean that the results are erroneous — publications in *Nature Medicine* undergo rigorous peer review. They do, however, require heightened critical reading, particularly regarding the selection of endpoints, interpretation of borderline results, and reporting of negative data.

Recurrent Methodological Limitations

1. Small sample sizes: Depommier 2019 (n = 32), Zhang 2025 (n = 58). These sample sizes, sufficient for an exploratory signal, are inadequate for definitive conclusions and for detecting infrequent adverse effects.

2. Short durations: All published studies have a maximum duration of 12 to 24 weeks. No data beyond 6 months in humans. Impossibility of evaluating durability, long-term safety, or impact on hard endpoints.

3. Probable publication bias: Three large completed trials (NCT05114018, NCT05348642, PAM-DIGEST) have not yet published their results in a peer-reviewed journal. If their results were positive, they would likely have been published promptly — their absence from the literature may indicate neutral or negative results, representing a potentially significant publication bias.

4. Strain heterogeneity: Live MucT, pAKK MucT, live WST01, Pendulum 5-strain formulation, pAKK_LWHK0003 — comparing these forms is virtually impossible. No direct head-to-head trial is available.

5. Absence of hard endpoints: No trial has assessed confirmed T2D incidence, major cardiovascular events (MACE), mortality, or long-term quality of life. All endpoints are intermediate biomarkers.

6. ApoB not measured: In all trials reporting a lipid benefit, ApoB — the foremost cardiometabolic lipid marker — has never been measured.

Bias Type	Trials Affected	Estimated Impact
Funding / conflict of interest	All interventional trials	High
Publication bias	NCT05114018, NCT05348642, PAM-DIGEST unpublished	High potential
Participant selection (low baseline AKK)	Zhang 2025, Mount 2026	Medium
Placebo effect	NCT05348642 (IBS)	Dominant
Measurement bias (non-standardised methods)	All observational cohorts	High

8. Pragmatic Conclusion

For Whom Supplementation Is Reasonably Discussable

On the basis of the evidence available in June 2026, two clinical profiles may reasonably be discussed with a healthcare professional:

1. **The overweight or pre-diabetic adult with a documented low baseline *A. muciniphila* level** (by metagenomic or 16S analysis), within the framework of a structured diet and behavioural management programme. The Mount 2026 signal on weight maintenance is the most convincing to date.
2. **The adult in the maintenance phase following weight loss under a structured programme**, in whom the baseline *A. muciniphila* level is documented as low. Limiting weight regain is a clinically relevant indication.

In both cases, the authorised dose is 3.4×10^{10} cells/day of pAKK MucT, for a maximum studied duration of 24 weeks. Supplementation does not replace first-line lifestyle measures under any circumstances.

For Whom Supplementation Remains Premature

- **IBD (Crohn's, UC):** Contradictory data, potential risk, no published human trial.
- **Longevity / neurodegenerative prevention:** Total murine extrapolation, no human interventional data.
- **NAFLD/MASLD:** No published human trial, first trial ongoing (results expected 2027).
- **Patients on ICI immunotherapy:** Observational signal only, no published randomised intervention, U-shaped relationship potentially dangerous without oncological supervision.
- **Pregnant, breastfeeding women:** EFSA exclusion maintained.

What to Watch in 2027

Three results could substantially modify the current assessment:

1. **NCT05114018** (A-Mansia, n = 144, dysglycaemia + metabolic syndrome, 6 months): if positive with sufficient statistical power, this will be the most powerful pre-diabetes trial ever published on *A. muciniphila*
2. **PAM-DIGEST** (n = 380, IBS-D): the largest *A. muciniphila* interventional RCT ever conducted — its results will redefine positioning in functional digestive disorders

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3. **NCT07488975** (MASLD, Asia): the first human interventional trial in hepatic steatosis — a domain of major public health significance

9. Frequently Asked Questions (FAQ)

What is *Akkermansia muciniphila*?

Akkermansia muciniphila is a gut bacterium belonging to the phylum Verrucomicrobiota, first described in 2004. It colonises the intestinal mucus layer, reinforces the intestinal barrier, stimulates GLP-1 secretion, and locally modulates immunity. It represents 1–4% of the healthy adult microbiome and tends to decrease in obesity, diabetes, and inflammatory diseases. It is currently the most extensively studied next-generation probiotic clinically in the world.

What is the difference between live and pasteurised *Akkermansia*?

The pasteurised form (pAKK) is a bacterium heated at 72 °C for 30 minutes, eliminating all viability. It is the only form authorised as Novel Food in the EU (Regulation 2022/168) and the only form to have demonstrated significant clinical efficacy in randomised trials (Depommier 2019). The live form, tested in parallel in the same trial, showed no significant effect — suggesting that efficacy rests on membrane components (notably the Amuc_1100 protein) and not on viability. The live form has no EU Novel Food authorisation to date.

Should one take an *Akkermansia* supplement?

For the vast majority of healthy individuals, no. A diet rich in polyphenols (red berries, green tea, pomegranate), prebiotic fibres (chicory, artichokes, legumes), and omega-3 fatty acids is the best way to maintain natural *A. muciniphila* abundance. Supplementation may be discussed with a physician for an overweight or pre-diabetic adult with a documented low baseline level, within a structured management programme. Outside this context, no evidence justifies supplementation.

Is *Akkermansia* authorised in the UK?

The FSA/FSS completed a positive safety assessment (RP1468) for pAKK in September 2024, for individuals aged 12 years and over at a maximum dose of 4×10^{10} cells/day. However, the required statutory instrument had not yet been gazetted as of June 2026, meaning the product is technically not yet formally authorised for sale in Great Britain.

Which product to choose — Pendulum or The Akkermansia Company?

These two brands are not directly comparable. **The Akkermansia Company** markets a pure pAKK MucT, compliant with EU Novel Food 2022/168, available in Europe. **Pendulum Glucose Control** (USA) is a 5-strain synbiotic including *A. muciniphila* WB-STR-0001, marketed as a Medical Food by prescription in the United States — not legally available in the EU in this format. No head-to-head trial has compared the two products. In the EU and UK, only the pAKK compliant with Novel Food EU is legally marketable.

Does *Akkermansia* cause weight loss?

Not directly. Clinical trials have not demonstrated significant active weight loss. However, the Mount 2026 trial (*Nature Medicine*) showed that pAKK significantly reduces *weight regain* after a slimming diet (–3.1 kg net vs placebo over 24 weeks), but only in individuals with a low baseline *A. muciniphila* level. It is therefore not a "fat burner" but potentially an adjunct weight maintenance tool in a very targeted context.

Akkermansia and diabetes: is the evidence sufficient?

Promising but insufficient for an established therapeutic recommendation. The Depommier 2019 trial demonstrated an improvement in insulin sensitivity in pre-diabetes, and Zhang 2025 confirmed a signal in T2D conditional on low baseline level. However, sample sizes remain small, durations short, structural conflicts of interest are present, and no hard endpoints (T2D incidence, CV events) have been assessed. The GRADE evidence level is **Moderate** for insulin sensitivity and **Low** for HbA1c in established T2D.

Akkermansia and cancer: what do we know?

A robust observational association exists between *A. muciniphila* presence in the microbiome and better response to anti-PD-1 immunotherapy, documented across four independent observational cohorts (Routy 2018, Derosa 2022, Grenda 2022, and 2023–2025 cohorts). However, **no randomised interventional trial** has proven that supplementation with *A. muciniphila* improves immunotherapy response. Moreover, abundance above 4.8% is associated with worse prognosis (Derosa 2022). Supplementing in an oncological context without medical advice is potentially dangerous.

Are there contraindications to taking *Akkermansia*?

Absolute contraindications: pregnancy, breastfeeding (EFSA exclusion — insufficient safety data). Situations requiring prior medical advice include: active IBD, severe immunosuppression, ICI anti-PD-1/PD-L1 therapy, active bacterial *Salmonella* infection. The pasteurised form is considered safe based on current data for healthy adults aged 18–70, at the authorised dose of 3.4×10^{10} cells/day.

How to increase *Akkermansia* without supplements?

The best-documented dietary strategies for naturally increasing *A. muciniphila* are: consuming foods rich in polyphenols (red berries, cranberry, green tea, pomegranate), increasing intake of fermentable prebiotic fibres (chicory, artichokes, FOS, inulin), and including omega-3 fatty acids (oily fish, flaxseed). Conversely, ultra-processed food, excess alcohol consumption, and unjustified antibiotic use are associated with a decrease in *A. muciniphila*.

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