

Probiotic Adverse Event Report — Documentation Template

Use this template to capture all data needed for internal pharmacovigilance review and for submission to FDA MedWatch (US), EU national authorities / RASFF (EU contamination), MHRA Yellow Card (UK), Livsmedelsverket / Läkemedelsverket (SE), or the manufacturer. Complete every field — missing strain, lot, or timing data is the most common reason a report is rejected.

1 — Reporter & Patient Identifiers

Report date	_____	Internal report ID	_____
Reporter name	_____	Role / credentials	_____
Institution	_____	Contact (phone / email)	_____
Patient ID (de-identified)	_____	Age / Sex	_____
Weight (kg)	_____	Pregnancy status	_____

2 — Product Identification (strain-level — REQUIRED)

Brand / product name	_____	Manufacturer	_____
NDC / GTIN / EAN	_____	Country purchased	_____
Lot / batch number	_____	Expiry date	_____
CFU per dose (label)	_____	Dosage form	_____
Storage at point of use	_____	Product retained for testing?	_____

Strain(s) — list every strain on the label, with full taxonomic designation:

#	Genus / species	Strain designation (e.g. CNCM I-745, ATCC 53103)	CFU contribution
1			
2			
3			
4			

3 — Dosing & Exposure

Indication for use	_____	Prescribed / self-initiated?	_____
Dose per administration	_____	Frequency	_____
Route	_____	Total daily CFU	_____
Date of first dose	_____	Date of last dose	_____
Total duration of use	_____	Doses missed?	_____
Co-administered antibiotics	_____	Other supplements / drugs	_____

4 — Patient Risk Factors at Time of Exposure

- | | | |
|---------------------------------------------------------------|---------------------------------------------------------------|------------------------------------------------------|
| <input type="checkbox"/> Central venous catheter / port | <input type="checkbox"/> Severe immunosuppression | <input type="checkbox"/> Prosthetic heart valve |
| <input type="checkbox"/> Short bowel syndrome | <input type="checkbox"/> Severe acute pancreatitis | <input type="checkbox"/> Preterm / NICU patient |
| <input type="checkbox"/> Active GI mucosal injury / mucositis | <input type="checkbox"/> Chemotherapy or stem-cell transplant | <input type="checkbox"/> Recent GI / cardiac surgery |
| <input type="checkbox"/> Age \geq 75 years | <input type="checkbox"/> Pregnancy | <input type="checkbox"/> Infant < 12 months |
| <input type="checkbox"/> Chronic steroids / biologics | <input type="checkbox"/> Inflammatory bowel disease (active) | <input type="checkbox"/> None identified |

Other relevant comorbidities / medications

5 — Adverse Event Timeline

Date / time symptoms began	_____	Time from first dose to onset	_____
Time from last dose to onset	_____	Date / time product stopped	_____
Date / time medical care sought	_____	Setting (clinic / ED / inpatient / ICU)	_____
Event resolution date	_____	Outcome (resolved / ongoing / fatal)	_____

Chronological narrative — one row per event/intervention:

Date	Time	Event / intervention	Notes

6 — Symptoms & Severity

- | | | | |
|-----------------------------------------------------|-------------------------------------------------|---------------------------------------------|--------------------------------------------------|
| <input type="checkbox"/> Bloating / flatulence | <input type="checkbox"/> Abdominal pain | <input type="checkbox"/> Diarrhea | <input type="checkbox"/> Constipation |
| <input type="checkbox"/> Nausea / vomiting | <input type="checkbox"/> Rash / urticaria | <input type="checkbox"/> Pruritus | <input type="checkbox"/> Anaphylaxis |
| <input type="checkbox"/> Fever \geq 38.5 °C | <input type="checkbox"/> Hypotension / shock | <input type="checkbox"/> New cardiac murmur | <input type="checkbox"/> Encephalopathy / ataxia |
| <input type="checkbox"/> Catheter-site inflammation | <input type="checkbox"/> Positive blood culture | <input type="checkbox"/> D-lactic acidosis | <input type="checkbox"/> Death |

Seriousness criteria (CIOMS / FDA) — tick all that apply:

Death

Life-threatening

Hospitalization / prolonged stay

Persistent or significant disability

Congenital anomaly / birth defect

Required intervention to prevent permanent impairment

Other medically important event

None — non-serious

Free-text symptom narrative (onset, evolution, character, severity 1–10)

7 — Diagnostics & Microbiology

Test	Date	Result	Lab / reference range
CBC w/ differential			
CRP / procalcitonin			
Blood culture #1			
Blood culture #2			
Catheter tip culture			
Stool culture / PCR			
Imaging (echo/CT/US)			
Strain ID method (MALDI / 16S / WGS)			
ANI vs product isolate (%)			
Resistance gene scan			
Other			

8 — Management & Treatment

Probiotic stopped (date/time, dechallenge response)

Empiric antimicrobials (drug, dose, route, duration) — note vancomycin AVOIDED for Lactobacillus

Source control (line removal, drainage, surgery)

Supportive care / ICU interventions

9 — Causality Assessment

Certain

Probable / likely

Possible

Unlikely

Unassessable

WHO-UMC factors:

Plausible time relationship

Cannot be explained by disease/other drugs

Dechallenge response (improvement on stop)

Rechallenge response (recurrence on restart)

Strain identity confirmed (ANI \geq 99.9%)

Known mechanism for this strain

10 — Regulatory & Internal Reporting

Channel	Submitted? (Y/N)	Date	Reference / case ID
FDA MedWatch (3500 / 3500B)			
FDA Safety Reporting Portal (mandatory SAE)			
RASFF (EU contamination)			
EU national competent authority			
MHRA Yellow Card (UK)			
Livsmedelsverket (SE — food)			
Läkemedelsverket (SE — medicinal)			
Manufacturer pharmacovigilance			
Internal pharmacy / IPC / AMR stewardship			
EARS-Net / CDC AR Lab Network			

Retain: remaining product, original packaging, lot label, receipt, refrigeration log, and any patient isolates for at least 12 months or until case closure. Quarantine remaining doses from the same lot pending manufacturer / regulator instruction.

Reporter signature

Date
