Probiotic Safety Monitoring Checklist

Clinical visit aid — pre-prescription screening, in-visit monitoring, and adverse event triage. Companion to Module 10 (Probiotics, Prebiotics & Synbiotics).

Patient ID / initials:		Date:	
Indication:		Visit type:	Initial / Follow-up
Product (brand):		Strain designation:	
Lot number:		Dose / CFU:	
Start date:		Planned reassessment:	

1. Pre-prescription screening (absolute & relative contraindications)

- ☐ **Central venous catheter** in situ or planned (avoid *S. boulardii* on wards with CVCs — fungemia risk).
- ☐ **Severe acute pancreatitis** (PROPATRIA 2008: increased mortality 16% vs 6% — contraindicated).
- ☐ **Severe immunosuppression**: post-transplant on calcineurin inhibitors, neutropenia <500, advanced HIV (CD4 <200), active chemo with mucositis, prednisone ≥20 mg/day or biologics.
- ☐ **Prosthetic heart valve** or recent valve surgery (Lactobacillus endocarditis case reports).
- ☐ **Structural GI compromise**: short bowel syndrome, recent GI surgery / fresh anastomosis, severe active IBD flare, enterocutaneous fistula.
- ☐ **Premature neonate** (<37 wk) outside an established NICU protocol with GMP / pharmaceutical-grade product.
- ☐ **Pregnancy**: confirm strain has safety data in pregnancy.
- ☐ **Strain–population fit**: strain has published evidence in this indication and population? Product is GMP / third-party verified (USP, NSF, ConsumerLab)?
- ☐ Patient counselled on rationale, expected effect, common side effects, and red flags requiring contact.

2. In-visit monitoring (every follow-up while on probiotic)

- ☐ **GI tolerance**: bloating, diarrhea, cramping, constipation — onset, severity, trajectory.
- ☐ **Red-flag symptoms**: persistent fever, rigors, new heart murmur, unexplained malaise, neurological symptoms (confusion, ataxia, slurred speech → consider D-lactic acidosis in SBS).
- ☐ **Adherence & product**: same brand, strain, lot? Storage conditions adequate (refrigeration if required)?
- ☐ **Concomitant changes**: new antibiotics, immunosuppressants, central line placement, planned surgery — re-screen contraindications.
- ☐ **Effectiveness**: symptom diary, validated score (e.g., IBS-SSS, Bristol stool, AAD frequency) vs baseline.
- ☐ **Reassessment date** set — discontinue if no benefit by pre-defined endpoint (typically 4–8 weeks).

3. Adverse event triage — when something goes wrong

- ☐ **Suspected probiotic-related infection** (bacteremia, fungemia, endocarditis): STOP probiotic; draw blood cultures; **request lab to specifically identify Lactobacillus / Saccharomyces** (routine ID may miss); start empiric therapy; remove or evaluate central line.
- ☐ **D-lactic acidosis** (SBS + Lactobacillus, encephalopathy / ataxia, normal L-lactate but anion-gap acidosis): STOP Lactobacillus; bicarbonate; restrict simple carbohydrates; consider non-absorbable antibiotics.

- [ ] **Severe GI symptoms**: STOP product; rule out C. difficile, SIBO, infectious colitis.
- [ ] **Suspected contamination / mislabeling**: quarantine remaining product and lot; photograph label and lot number; preserve for regulator testing.
- [ ] Document: product name, manufacturer, strain designation, lot number, dose, dates of use, reaction onset and course, outcome, concomitant medications, comorbidities.

4. Reporting pathway (use ALL that apply)

- [ ] **Hospital / clinic incident report** filed within institutional timeframe.
- [ ] **USA**: FDA MedWatch (Form 3500/3500B) for voluntary AE; **FDA Safety Reporting Portal** for serious AE (death, life-threatening, hospitalisation, disability, congenital anomaly).
- [ ] **EU**: national competent authority (food safety / medicines agency); **RASFF** alert if product contamination, mislabeling, or pathogen identity issue suspected.
- [ ] **UK**: MHRA **Yellow Card** scheme.
- [ ] **Sweden**: Livsmedelsverket (food) and/or Läkemedelsverket (if marketed with medical claim).
- [ ] Manufacturer notified in writing; lot retained for their investigation.
- [ ] Follow-up report submitted with culture identification, WGS results, and patient outcome when available.

5. Documentation in the medical record

- [ ] Indication, evidence grade cited, and shared-decision conversation noted.
- [ ] Product brand, strain designation, lot number, dose, start date, planned stop / reassessment date.
- [ ] Screening checklist completed (this form attached or transcribed).
- [ ] Any adverse event, action taken, and report reference numbers.

Quick reference — minimum AE report dataset

Patient (age, sex, no PII) · Product brand + strain designation + lot number + dose + start/stop dates · Reaction description with onset and course · Outcome · Concomitant medications and comorbidities · Reporter contact.

Key references

• Besselink MGH et al. Probiotic prophylaxis in predicted severe acute pancreatitis: PROPATRIA. *Lancet* 2008;371:651–9.
• Rao SSC et al. Brain fogginess, gas and bloating: a link between SIBO, probiotics and metabolic acidosis. *Clin Transl Gastroenterol* 2018;9:162.
• Muñoz P et al. Saccharomyces cerevisiae fungemia: an emerging infectious disease. *Clin Infect Dis* 2005;40:1625–34.
• Zmora N et al. Personalized gut mucosal colonization resistance to empiric probiotics. *Cell* 2018;174:1388–405.
• Su GL et al. AGA Clinical Practice Guidelines on the Role of Probiotics in GI Disorders. *Gastroenterology* 2020;159:697–705.