Template

Label change alignment planner

Brand _____ Change notice date _____ Target go-live date _____ Owner _____

1 Change notice From Regulatory Affairs or Medical Affairs

What changed

_____

_____

New prescribing information version _____ **Effective date** _____

New data references

_____

Issued by _____ **Received by commercial training on** _____

2 Rep training Commercial training owns this lane

Step	Owner	Due	Done
Update the rep module			☐
Update the AI Roleplay referral scenario			☐
MLR or PRC review of both			☐
Reps certify on the new claims Until then, reps stay on current approved materials			☐
Rep training live on the new version			☐

3 MSL training Medical Affairs owns this lane

Medical Affairs updates and reviews its own training. Record only what it confirms.

Medical Affairs contact _____ **Target go-live** _____ **Version confirmed** _____ **Confirmed on** _____

☐ **Change notice shared** ☐ **Referral scenario shared**

Notes for the next label change

_____

_____

_____

4 Referral scenario Pass-or-fail checks for the AI Roleplay attempt

- ☐ **Required safety statements, with fair balance**
- ☐ **Unapproved use not discussed**
  Discussing it fails the attempt
- ☐ **Medical Information request offered**
  Following your company's process
- ☐ **Question not invited, no MSL visit promised**

Pass mark for the scored checks _____

Pass rate during certification, round 1 _____ **Round 2** _____

Before the build

- ☐ Route checked with compliance
- ☐ Referral wording checked by Medical Information

5 Version check Before go-live and again at go-live

Asset	Owner	Cites	Status
			☐ Match ☐ Retire
			☐ Match ☐ Retire
			☐ Match ☐ Retire
			☐ Match ☐ Retire
			☐ Match ☐ Retire
MSL program	Medical Affairs		☐ Match ☐ Retire

Confirm the MSL row by version number only. Commercial training doesn't open MSL content.

6 At go-live

- ☐ **Old version retired from every module, scenario and slide**
- ☐ **Every rep certified, including the referral gate, before using new claims**

Rep go-live on _____ **MSL go-live confirmed on** _____

Most common referral miss _____