HealthLiteracyCopilot™

Business case kit for pharma and life sciences: take clear patient communication to senior management

For the Medical writing or patient-services lead taking a case to the Head of medical or regulatory affairs, or the brand P&L owner: the questions they ask first, the top problems sized with your numbers, a one-page template, the hurdle check and a 10-slide deck outline. All of it is on this page.

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A planning aid, not financial advice. Every number is a source with its year, your own input or a labeled synthetic example.

What senior management asks first

The Head of medical or regulatory affairs, or the brand P&L owner will ask these seven questions, in about this order. The case below answers each one. Your champion is usually the Medical writing or patient-services lead, and the budget line is medical writing and MLR review, or patient services.

- What problem, and how big is it in our money? The top problem for your segment, sized with your own inputs.
- Why now? A dated external pressure: a rule, a rating release or a deadline, with its source.

- What does it cost us, all in? The program cost from your quote, plus the reviewer time the pilot takes.
- What return do we need, and is that plausible? Your hurdle times the program cost, and the share of each cost pool that would have to change.
- How will we know it worked, and when? A baseline, then revised against current, with the measure and the decision rule chosen before it starts.
- What could go wrong, and what don't you promise? Security, PHI handling and human review, and a plain list of what is not promised.
- What exactly are you asking us to approve? One sentence: the documents, the 90 days, and the rule that decides at day 90.

The top problems for pharma and life sciences, and how to size them

Each problem has a sourced fact and a formula to size it with your own numbers. Rating and penalty money is context for the case: it depends on a rating, so it is never counted as a saving.

Problem	What we know	Source	Size it with your numbers
Writer and reviewer hours per asset	FDA's ad office, OPDP, posted 63 untitled letters in 2025, against 5 in 2024 and 4 in 2023. Many cite risk information that is minimized or presented in a way that is hard to take in.	FDA, Untitled Letters to pharmaceutical companies, 2025; Hall Render, A turning point for OPDP (2025-12-22), on what the letters cite, 2025	Documents a year × reviewer hours per document × loaded hourly rate. The calculator also gives the break-even minutes per document. The calculator at /roi/writer-reviewer-hours does this for you.
Non-adherence	About 50% of patients with long-term	World Health Organization,	Patients on therapy × your adherence

Problem	What we know	Source	Size it with your numbers
	conditions in developed countries don't take medicines as prescribed. An estimated $290 billion a year in avoidable US costs (a 2009 estimate) is linked to medication non-adherence.	Adherence to Long-Term Therapies, 2003; NEHI (New England Healthcare Institute), 2009	gap × the value you assign to an adherent patient-year. This is value from better adherence, not a cost today.
Lay summaries and patient labeling	Since 2025-01-31, every clinical trial of a medicine in the EU and EEA runs under the Clinical Trials Regulation and must post a summary of its results written for the public. FDA has proposed one-page Patient Medication Information for outpatient prescription drugs.	Regulation (EU) No 536/2014, Article 37 and Annex V, 2014; FDA, Patient Medication Information proposed rule (Federal Register, 2023-05-31), 2023	Summaries or guides a year × writer and reviewer hours each × loaded hourly rate. The calculator at /roi/writer-reviewer-hours does this for you.

Why now

Lead with a dated pressure. Pick the one closest to your budget line.

- OPDP untitled letters rose from 4 in 2023 and 5 in 2024 to 63 in 2025. (FDA, Untitled Letters to pharmaceutical companies, 2025; Hall Render, A turning point for OPDP (2025-12-22), on what the letters cite, 2025)
- FDA's Fall 2025 regulatory agenda lists the Patient Medication Information final rule for December 2026: a target date, not a final rule. (Unified Agenda of Federal Regulatory Actions, Fall 2025, FDA, RIN 0910-AH68, 2025)

The business case on one page

Nine fields, each labeled with the kind of evidence it carries. "Modelled" means your inputs through a stated formula; "Measured at day 90" means the pilot produces it.

Field	What goes in it	Evidence label
The ask	One sentence: approve a 90-day measured pilot on your highest-volume documents, and decide at day 90 by a rule agreed first.	—
The problem, in our numbers	The top problem for your segment, sized with your own inputs.	Modelled
Why now	The dated external pressure: a rule, a rating release or a deadline.	Source and year
Cost today	Each cost pool from the matching calculator, kept separate. Never add them into one saving.	Modelled
What we will change	The documents in scope, the standards used, human review and the review record.	—
The hurdle	Program cost × your hurdle = value needed, and the share of each pool that would have to change.	Modelled
How we will prove it	A baseline, then revised against a holdout. Efficiency first, then understanding, then an outcome.	Measured at day 90
Risks and limits	The security sentence, PHI handling, human review and what is not promised.	—
Decision	The owner, the date and the day-90 decision rule.	—

Fill in your one page

Write your own entry for each field, then download it as a CSV for your deck. For pharma and life sciences, the documents in scope are usually your highest-volume

patient-facing assets: medication guides, patient-support pieces and lay summaries. Nothing you type leaves this page.

Field	Your entry	Evidence label or source
The ask		
The problem, in our numbers		
Why now		
Cost today		
What we will change		
The hurdle		
How we will prove it		
Risks and limits		
Decision		

The hurdle check

Finance will ask what return the program has to earn. Don't quote one: compute what would have to change. Value needed = annual program cost × your hurdle (the return your finance team asks for, such as 3 to 1 or 4 to 1). Share of a pool = value needed ÷ that cost pool. Over 100% means that pool alone can't clear the hurdle. Of the pools the pilot can measure, the one that needs the smallest share to change is where to measure first. Say whether each pool is cash or staff time. Finance counts staff time only if spending falls, such as overtime, temp or vendor

cost. If finance gives a payback period instead, a 12-month payback is a hurdle of 1 to 1. Synthetic health-plan example: not a customer's numbers and not a quote. Program cost $60,000 a year at a hurdle of 4 to 1: $240,000 of value needed.

Cost pool (synthetic)	Pool a year	Share that would have to change
Member-notice call pool (200,000 members ÷ 1,000 × 400 calls per 1,000 × $8.01)	$640,800	37% of it would have to change.
Template review pool (300 templates × 3 cycles × 4 hours × $95)	$342,000	70% of it would have to change.

The sample deck, slide by slide

Ten slides, one question each. Blanks are yours to fill from the calculator and your quote. Every money or share line carries its evidence label. In this synthetic example, the call pool needs a 37% change to clear the hurdle and the review pool 70%. So the pilot measures calls about the revised notice against a holdout, and reports reviewer hours alongside.

Slide	What it says	Evidence label
1. The ask	Approve a 90-day measured pilot of HealthLiteracyCopilot on your highest-volume patient-facing assets: medication guides, patient-support pieces and lay summaries. Decide on expansion at day 90 by a rule we agree before it starts. Approver: Head of medical or regulatory affairs, or the brand P&L owner. Champion: Medical writing or patient-services lead. Budget line: Medical writing and MLR review, or patient services.	—
2. The problem in our numbers	Writer and reviewer hours per asset. FDA's ad office, OPDP, posted 63 untitled letters in 2025, against 5 in 2024 and 4 in 2023. Many cite risk information that is minimized or presented in a way that is hard to take in. Size it: Documents a	FDA, Untitled Letters to pharmaceutical companies, 2025; Hall Render, A turning point for OPDP (2025-12-22),

Slide	What it says	Evidence label
	year × reviewer hours per document × loaded hourly rate. The calculator also gives the break-even minutes per document. Our number: _____ a year	on what the letters cite, 2025; Modelled
3. Why now	OPDP untitled letters rose from 4 in 2023 and 5 in 2024 to 63 in 2025. FDA's Fall 2025 regulatory agenda lists the Patient Medication Information final rule for December 2026: a target date, not a final rule.	FDA, Untitled Letters to pharmaceutical companies, 2025; Hall Render, A turning point for OPDP (2025-12-22), on what the letters cite, 2025; Unified Agenda of Federal Regulatory Actions, Fall 2025, FDA, RIN 0910-AH68, 2025
4. Cost today	Writer and reviewer hours per asset: Documents a year × reviewer hours per document × loaded hourly rate = _____ Lay summaries and patient labeling: Summaries or guides a year × writer and reviewer hours each × loaded hourly rate = _____ Keep each pool separate. Never add them into one saving.	Modelled
5. What we will change	Revise your highest-volume patient-facing assets: medication guides, patient-support pieces and lay summaries to IHA's N-PLAT, AHRQ's PEMAT and a reading grade you set. Your reviewers approve every change, and each version keeps a review record: the criteria, the reviewer and the date. The documents need no PHI: we work from templates and samples.	—
6. The hurdle	Value needed = annual program cost × your hurdle (the return your finance team asks for, such as 3 to 1 or 4 to 1). Share of a pool = value needed ÷ that cost pool. Over 100% means that pool alone can't clear the hurdle. Of the pools the pilot can measure, the one that needs the smallest share to change is where to measure first. Say whether each pool is cash or staff	Method; Modelled

Slide	What it says	Evidence label
	time. Finance counts staff time only if spending falls, such as overtime, temp or vendor cost. If finance gives a payback period instead, a 12-month payback is a hurdle of 1 to 1. Program cost _____ × hurdle _____ = value needed _____	
7. How we will prove it	Baseline first, then the revised documents against a holdout. We pick the measure and the decision rule before the pilot starts. Efficiency: MLR review cycles and hours per asset. Understanding: Grade, PEMAT and N-PLAT on the revised assets, and patient-services calls. Outcome: Refill persistence on a split program, measured by the brand's own method.	Measured at day 90
8. Risks and limits	HealthcareGPS is SOC 2 Type II audited and HIPAA compliant. No PHI goes into prompts. We work from templates and samples. AI drafts; your reviewers decide. Nothing is sent without their approval.	—
9. What we don't promise	We don't promise an adherence change or a shorter MLR cycle. We measure hours and cycles per asset, and test the measure you pick.	—
10. Decision and next steps	Owner: _____ Decision date: _____ Day-90 rule, for example: expand if the measured cut in the chosen pool is at least the share the hurdle needs, and the 95% interval excludes zero. Size the groups so the test can detect that cut. Next step: agree the documents in scope and the measure.	Your rule, set before the pilot

The 90-day pilot that proves it

Measure in this order, on a baseline and then revised against current. Choose the measure and the decision rule before the pilot starts. We don't promise an

adherence change or a shorter MLR cycle. We measure hours and cycles per asset, and test the measure you pick.

- Efficiency: MLR review cycles and hours per asset
- Understanding: Grade, PEMAT and N-PLAT on the revised assets, and patient-services calls
- Outcome: Refill persistence on a split program, measured by the brand's own method

Sources

- FDA, Untitled Letters to pharmaceutical companies, 2025
- Hall Render, A turning point for OPDP (2025-12-22), on what the letters cite, 2025
- World Health Organization, Adherence to Long-Term Therapies, 2003
- Regulation (EU) No 536/2014, Article 37 and Annex V, 2014
- FDA, Patient Medication Information proposed rule (Federal Register, 2023-05-31), 2023
- Unified Agenda of Federal Regulatory Actions, Fall 2025, FDA, RIN 0910-AH68, 2025

Questions

Can't our team just use ChatGPT?

General AI can change a dose, a date or a disclaimer. HealthLiteracyCopilot keeps protected terms word for word, checks clinical anchors, never grades its own revisions, and keeps a review record for every version.

We tried plain language before and nothing changed. Why is this different?

This is a measured pilot: a baseline, a holdout, and a measure and decision rule you choose before it starts. If the revised documents don't move your measure, the case says so.

Is it safe with member or patient data?

HealthcareGPS is SOC 2 Type II audited and HIPAA compliant. The documents themselves need no PHI: we work from templates and samples.

Will this raise our Star Rating, HCAHPS or adherence?

No one can promise that, and we don't. We test the measure you pick on your own members or patients, and report what changed.

What does it cost, all in?

The program cost on your quote, plus your reviewers' time during the pilot. Add that time to the program cost before you apply the hurdle.

HealthLiteracyCopilot™

Next: Get a free assessment of one document

www.healthliteracycopilot.ai/assess

Send a blank template, not a copy with a patient's or member's details.

HealthcareGPS is SOC 2 Type II audited and HIPAA compliant.

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