

Quantifying the Return on Investment of Medical Affairs in the AI Era

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Abstract

Artificial intelligence (AI) is entering pharmaceutical Medical Affairs (MA) across medical writing, evidence generation, medical information, medical education, scientific communications, and field medical operations, changing how the function creates and delivers value. Yet MA has never had a standardised financial framework for measuring return on investment (ROI) comparable to those established in R&D and Commercial. Without such a framework, the additional value generated through AI adoption, and whether it justifies the associated investment, cannot be quantified.

This paper presents the Medical Affairs Value Index (MAVI), a tool to quantify MA's ROI and assess how AI modifies it. MAVI integrates a Positive ROI model capturing value creation through revenue acceleration, cost avoidance, pipeline de-risking, and strategic option value, operationalised as a benefit–cost ratio, with a Reverse ROI model that quantifies the enterprise cost of MA underinvestment through probability-weighted loss estimation. Attribution coefficients for both upside (α MA) and downside (β MA) are introduced with governance safeguards. The primary output is a two-dimensional value map.

AI is unlikely to materially reduce the cost of MA operations; it reallocates spending from manual activities to AI-augmented workflows, keeping the cost denominator approximately flat while the benefit numerator grows. An illustrative scenario demonstrates that under evidence-based assumptions, MAVI reveals a Positive ROI above breakeven before AI adoption, with AI further amplifying the return. The Reverse ROI, capturing enterprise losses MA helps prevent, remains broadly stable across both scenarios. MAVI provides the financial architecture to quantify both dimensions and track how AI modifies them over time.

KEY POINTS

- 1) Medical Affairs (MA) lacks a standardised financial framework for measuring return on investment, a gap now compounded by AI's capacity to amplify MA output without proportionally reducing cost.
- 2) The Medical Affairs Value Index (MAVI) integrates a Positive ROI model (benefit–cost ratio capturing value creation) with a Reverse ROI model (probability-weighted enterprise losses prevented), reported as a two-dimensional value map.
- 3) Attribution coefficients on both upside (α MA) and downside (β MA) govern how value is assigned to MA relative to co-producing functions, a requirement that becomes more demanding when AI is a co-producer.
- 4) AI is unlikely to materially reduce the cost of MA operations; it reallocates spending from manual tasks to AI-augmented workflows while introducing new cost lines for tools and governance. The cost denominator remains approximately flat while the benefit numerator grows. MAVI provides the framework to quantify this shift and assess its impact on both value creation and risk prevention.

5) Without a financial measurement framework, neither the baseline value MA creates nor the additional value AI enables is visible to decision-makers. MAVI provides the architecture to quantify both

1. INTRODUCTION

1.1 AI IN MEDICAL AFFAIRS

Artificial intelligence is entering pharmaceutical operations across the product lifecycle. The McKinsey Global Institute estimates that generative AI could generate US\$60–110 billion annually in economic value for the pharmaceutical and medical-product industries, with applications spanning research, clinical development, operations, commercial, and medical affairs.[1] AI adoption is already visible in adjacent functions: a landscape analysis of FDA regulatory submissions documented a growing number of drug and biologic applications incorporating AI and machine learning components between 2016 and 2021.[2] Within MA, AI is being applied across medical writing and publications, evidence generation and real-world evidence analysis, medical information inquiry handling, medical education, scientific communications, and field medical operations including MSL preparation and insight capture.[3–5]

Taken together, these developments are shifting the operational profile of MA functions, changing which tasks require human effort, how much output a given team can produce, and what skill mix is needed. Without a framework for measuring the financial impact of these changes, organisations lack the basis for informed decisions about MA investment, workforce planning, and the governance of AI-augmented workflows.

1.2 THE MEASUREMENT GAP

MA has been recognised as a strategic function alongside R&D and Commercial,[6, 7] with growing attention to the value it brings to patients and to the organisations that invest in it.[8] Unlike its peer functions, however, MA has never had a standardised financial model for demonstrating its contribution. For example, Commercial can quantify value through revenue attribution and market share analysis, while R&D uses net present value (NPV) and probability-of-success models to justify investment decisions. MA, by contrast, typically reports activity-based metrics, like MSL interaction counts, publication numbers, medical information response volumes, or qualitative narratives without financial granularity.[9, 10]

This asymmetry becomes more consequential as AI enters MA operations. AI automates the tasks that produce countable output (literature reviews, response documents, evidence summaries) but the strategic contributions that drive organisational value (scientific judgement, regulatory credibility, evidence strategy) remain unmeasured.[11] The result is that AI increases what MA produces without providing a mechanism to quantify what that increased production is worth. Without a financial framework, the increased output cannot be translated into the financial terms required for resource-allocation decisions

Industry bodies have developed increasingly sophisticated approaches,[9, 12, 13] including multi-stakeholder value models[11, 14]and validated workforce instruments.[15] None, however, provides a financial framework for quantifying the value MA creates, nor a basis for understanding how AI may amplify or transform that value. Six gaps persist: (1) incomplete value capture, particularly the cost of underinvestment; (2) attribution challenges in co-created value; (3) misalignment between multi-year returns and annual budget cycles; (4) insufficient financial rigour; (5) sector-specific variation; and (6) AI-readiness.

1.3 OBJECTIVE

This paper presents the Medical Affairs Value Index (MAVI), a tool developed to quantify MA's return on investment and to explore how AI is impacting its ROI. The central proposition is that AI can increase MA's Positive ROI, not by reducing cost, but by increasing the output the same cost produces, while strengthening the risk-governance case. However, this additional value is not captured without a measurement framework that governs attribution. MAVI provides both the measurement architecture and the attribution governance.

MAVI is deliberately structured as a multi-component index rather than a single score: its principal output is a two-dimensional value map that allows organisations to assess MA's contribution on both value creation and risk prevention simultaneously. The framework is conceptual and designed for progressive organisational calibration; its immediate purpose is to provide a structured basis for investment discussions, not a definitive decision threshold. Although illustrated with pharmaceutical examples, MAVI is intended for MA functions across biopharma and MedTech.

2. MAVI: MEASURING MA ROI

Figure 1 provides a conceptual overview of the MAVI framework. The notation glossary (Table 1) defines all symbols. The evidence search methodology is documented in ESM File S2.

Table 1
MAVI framework notation glossary

Symbol	Name	Definition	Units / Range
αMA	Upside attribution	Fraction of revenue value attributable to MA; set via governed process	$0 < \alpha MA \leq 1$
$\beta MA, k$	Downside attribution	Fraction of loss category k preventable by MA	$0 < \beta MA \leq 1$
ΔRev_t	Incremental revenue	Revenue acceleration vs. counterfactual in period t	US\$ per period
CA_t	Cost avoided	Expenditures averted through MA in period t	US\$ per period
$\Delta rNPV_t$	Risk-adjusted NPV Δ	Change in risk-adjusted NPV from MA de-risking	US\$ per period
SOV_t	Strategic option value	Option premium from MA-enabled future choices	US\$ per period
OverlapAdj _t	Overlap adjustment	Deduction for double-counted value (Eq. 1a)	US\$ per period
r	Discount rate	Organisation's WACC	8–12%
T	Evaluation horizon	Periods for discounted analysis	3–5 years
$P(Loss_{k,t})$	Loss probability	Event probability absent adequate MA	0–1
CorrAdj	Correlation adj.	Deduction for non-independence (Eq. 2a; PV-denominated; applied after discounting)	US\$

2.1 Positive ROI model

The Positive ROI captures measurable financial value attributable to MA over a T-period evaluation horizon using discounted cash-flow methodology, operationalised as a benefit–cost ratio ($BCR = PV(Benefits)/PV(Cost)$). Net ROI = $BCR - 1$ is reported alongside all BCR values for interpretability.

Equation 1a, Present value of MA-attributable benefits:

$$PV(Benefits_{MA}) = \sum_{t=1}^T [(\alpha MA \times \Delta Rev_t) + CA_t + \Delta rNPV_t + SOV_t - OverlapAdj_t] \times (1 + r)^{-t}$$

Equation 1b, Present value of MA investment:

$$PV(Cost_{MA}) = \sum_{t=1}^T [MA_Cost_t] \times (1 + r)^{-t}$$

Equation 1c, Positive ROI:

$Positive\ ROI = PV(BenefitsMA) / PV(CostMA)$

Each component (Table 2) represents a distinct value channel. The coefficient αMA ($0 < \alpha MA \leq 1$) is applied to $\Delta Revenue$, where cross-functional co-creation with Commercial is most pronounced; ΔRev should be operationalised as incremental contribution margin, not gross revenue. The remaining components (CA (cost avoided), $\Delta rNPV$ (risk-adjusted NPV change from pipeline de-risking), and SOV (strategic option value)) capture only the MA-attributable portion by construction, subject to the documentation requirements in Box 1. Table 3 proposes indicative αMA ranges by activity type.

Table 2
Positive ROI component definitions and benchmarks

Component	Definition	Operationalisation	Key Benchmark
$\alpha MA \times \Delta Rev_t$	Incremental net sales (MA-attributed fraction)	Comparator launch matching, time-to-adoption	IQVIA [19] (grey; vendor; illustrative)
CA _t	MA-attributable expenditures prevented (Box 1)	Historical cost tracking; MA ownership documented	~\$535K/Phase III amendment [20]
$\Delta rNPV_t$	MA-attributable change in asset value (Box 1)	$\Delta PoS \times NPV \times$ discount; documented assumptions	PoS data [21, 22]
SOV _t	MA-attributable option premium (Box 1)	Binomial lattice at decision gates; incremental	Real options methodology
OverlapAdj _t	Deduction for double-counted value	Mapping rules or 15–25% haircut	Organisation-specific
Reference numbers correspond to the main manuscript reference list.			

BOX 1. Operational Rules for "Attributable by Construction"

- Components CA, $\Delta rNPV$, and SOV bypass αMA only when each claimed item satisfies all four criteria:
- (i) **Documented MA ownership:** a named MA individual or team led or co-led the activity, evidenced by project records, approval chains, or RACI matrices.
 - (ii) **Counterfactual plausibility:** management can articulate why the outcome would not have occurred (or would have been materially worse) without MA involvement.
 - (iii) **Exclusion of shared credit:** if another function has an equal or greater claim, the item must be resolved by: (a) applying an explicit attribution factor agreed with the co-owning function (analogous to αMA), (b) splitting the item by documented agreement and assigning each portion to the appropriate

component, or (c) excluding it entirely. Items should not be reclassified into a different component category to circumvent shared ownership.

(iv) Annual audit: items classified as "attributable by construction" are reviewed annually by the cross-functional governance panel (including Finance and Compliance). Items failing any criterion are reclassified.

(v) AI-generated outputs (added in v2): when AI tools contribute to an output claimed under CA, Δ rNPV, or SOV, the documentation must specify: (a) which AI tool was used and for which task; (b) the nature and extent of human review and modification; and (c) whether the strategic direction (which questions to answer, which populations to study, which endpoints to prioritise) was set by MA. AI-assisted execution does not transfer attribution to IT or data science if MA directed the strategy and validated the output.

Example of a failed Box 1 item: an MSL-facilitated investigator-initiated trial application where Commercial independently contacted the same investigator is classified as "shared credit" under criterion (iii) and receives an explicit attribution factor agreed between MA and Commercial, rather than claiming full CA attribution.

Items that do not meet these criteria should either receive an explicit attribution factor or be excluded from the calculation.

Table 3
Indicative α MA ranges by MA activity type

MA Activity Category	Indicative α MA	Rationale
KOL engagement and medical education	0.15–0.30	Substantial Commercial co-contribution
Protocol design and trial feasibility	0.20–0.40	MA contribution more isolable; R&D co-creation
RWE generation and evidence planning	0.30–0.50	MA typically leads; Market Access co-benefits
Post-market surveillance and safety	0.30–0.50	Relatively direct causal link to regulatory outcomes
IIT-driven label expansion	0.25–0.40	MA initiates; R&D executes submission
Medical information and congress	0.10–0.20	Diffuse impact; attribution difficult
<i>Expert-informed starting points for cross-functional calibration, not empirically validated parameters.</i>		

2.2 Reverse ROI model

The Reverse ROI quantifies expected enterprise losses when MA is eliminated or materially under-resourced, framing MA investment as risk governance.

Equation 2a, Present value of MA-preventable expected losses:

$$PV(\text{LossesNoMA}) = \sum_k \sum_{t=1}^T [\beta_{MA,k} \times P(\text{Loss}_{k,t}) \times \text{Impact}_{k,t} \times \text{Duration}_{k,t}] \times (1 + r)^{-t} - \text{CorrAdj}$$

Equation 2b, Present value of foregone MA budget:

$$PV(\text{Foregone MA Budget}) = \sum_{t=1}^T [\text{MA_Cost}_t] \times (1 + r)^{-t}$$

Equation 2c, Reverse ROI:

$$\text{Reverse ROI} = PV(\text{LossesNoMA}) / PV(\text{Foregone MA Budget})$$

The downside attribution coefficient $\beta_{MA,k}$ ($0 < \beta_{MA,k} \leq 1$) represents the fraction of each loss category that MA is credibly positioned to prevent. Table 4 Panel B proposes indicative β_{MA} ranges. Minimum reporting standards require documentation of probability sources, impact definitions, duration logic, and sensitivity analysis. The probabilities $P(\text{Loss}_{k,t})$ represent industry-level event frequencies, not conditional probabilities specific to MA underinvestment, which is a recognised limitation. Box 2 describes staged implementation for probability calibration. The correlation safeguard (CorrAdj) prevents double counting of co-occurring events.

Table 4
Evidence credibility and Reverse ROI loss categories Panel A: Evidence source credibility

Benchmark	Source Type	Credibility	Key Limitation	Ref
Protocol amendment cost (~\$535K)	Peer-reviewed	High	US-centric sample	[20]
Delay day value (\$500K–\$800K)	Peer-reviewed	High	Median varies by TA	[22]
Clinical PoS rates	Peer-reviewed	High	Historical; varies by TA	[21, 22]
R&D costs (\$2.6B capitalised)	Peer-reviewed	High	Industry-funded study	[23]
Launch benchmarks	Grey—vendor	Low–Medium	Potential commercial bias; illustrative only	[18]
Regulatory sanctions (\$1–10M)	Industry estimates	Low	Wide range; no single robust source; illustrative	
Product recall costs	Press / regulatory	Medium	Single-case examples	[24]
EU-MDR penalties	Regulation / legal	High (structure)	Monetary exposure jurisdiction-specific; applies to MedTech/combination-product MA	[25]
Panel B: Reverse ROI loss categories with indicative βMA				

BOX 2. Implementation Upgrade Path for Probability Modelling (Δ P Calibration)

Stage 1, Baseline frequency + conservative β MA

Use unconditional industry-level event frequencies from published sources (Table 4). Apply conservative β MA values from Table 4 Panel B. This is the lowest-data-requirement entry point and yields a pragmatic lower bound.

Stage 2, Internal incident log + empirical priors

Retrospectively analyse the organisation's own loss events over 3–5 years. Use these internal frequencies as Bayesian updates to the Stage 1 priors. For example, if the company has experienced two protocol-amendment events attributable to insufficient MA input in five years, this empirical rate ($2/5 = 0.40/\text{year}$) replaces the industry benchmark for that category.

Stage 3, Capability-specific Δ P estimation

Model partial under-resourcing rather than binary MA removal. Estimate the relative risk reduction (Δ P) associated with specific MA capabilities (e.g., pharmacovigilance staffing level, evidence-planning

maturity score). This allows modelling of investment increments (e.g., "+5 MSLs reduces launch delay probability by X%") rather than all-or-nothing scenarios. Structured expert elicitation (Delphi panels with Finance and Compliance) is the recommended calibration method at this stage.

AI-era note (added in v2): AI adoption may accelerate the transition from Stage 1 to Stage 2 by enabling systematic tracking of AI-augmented outputs and their outcomes. However, AI also introduces new loss categories (e.g., regulatory findings from inadequately reviewed AI-generated content) that may not have Stage 1 industry benchmarks. Organisations should document these emerging categories with conservative probability estimates until empirical data are available.

Organisations should document which Stage they are operating at and disclose this alongside reported Reverse ROI values. Migration from Stage 1 to Stage 3 is expected over 2–3 annual cycles.

2.3 The two-dimensional value map

MAVI is reported as a two-dimensional value map (Fig. 2), with Positive ROI (BCR) on the horizontal axis and Reverse ROI (β MA-adjusted) on the vertical axis. This format preserves the distinct information each dimension carries and avoids combining non-commensurable ratios into a single score. Dashed reference lines at 1.0 $\times$ on both axes mark breakeven: a Positive ROI above 1.0 $\times$ indicates that MA-attributable benefits exceed MA cost; a Reverse ROI above 1.0 $\times$ indicates that expected losses prevented exceed the MA budget that would be foregone.

Organisations positioned below breakeven on both axes face a diagnostic question: does the result reflect underperformance, or conservative measurement? Those above breakeven on risk prevention but below on value creation have a quantified case for MA as a governance function. The value map thus supports investment discussions grounded in evidence rather than in assumptions. To prevent double counting, each value stream is assigned to a single dimension (Table 5).

Table 5
Cross-panel mutual exclusivity: mapping rules and edge cases

Value Stream	Home Panel	Excluded From	Edge Case	Resolution
Protocol amendments avoided	Positive ROI (CA)	Reverse ROI	Residual amendment risk beyond MA input	Cap residual at 25% in Reverse ROI; document
Launch delay prevention	Reverse ROI	Positive ROI (Δ Rev)	Faster launch = revenue acceleration?	Revenue acceleration goes to Δ Rev; delay prevention stays in Reverse ROI as distinct pathway
Regulatory compliance costs avoided	Positive ROI (CA)	Reverse ROI	Sanctions from non-compliance?	Compliance costs avoided → CA; sanctions risk (distinct from CA) → Reverse ROI with β MA
Competitive displacement	Reverse ROI	Positive ROI (Δ Rev)	Evidence differentiation drives revenue?	Revenue from evidence → Δ Rev; chronic competitor gap (absent MA) → Reverse ROI
Product recall prevention	Reverse ROI	Positive ROI (CA)	Signal detection cost savings?	Operational savings → CA; catastrophic recall risk → Reverse ROI
Evidence-enabled label expansion	Positive ROI (Δ rNPV)	Reverse ROI	Missed expansion = lost revenue?	NPV appreciation → Δ rNPV; forfeited option excluded (subsumed in Δ rNPV counterfactual)
<p><i>When both panels have a legitimate claim, the upstream (more direct) pathway takes the home assignment. Downstream (indirect) pathways are capped at 25–50% and documented. The overriding principle: no dollar of claimed value appears twice in the two-dimensional value map.</i></p>				

Table 6

Illustrative scenario: pre-AI and AI-augmented (mid-size pharmaceutical company, T = 5 years, r = 10%)

Parameter	Pre-AI	AI-Era	Source / Basis
Portfolio revenue	US\$1B	US\$1B	Assumed
Annual MA investment	US\$18M (60 FTEs)	US\$18M (55 FTEs + \$2.5M AI)	Reallocation, not reduction
Time horizon (T)	5 years	5 years	Design choice
Discount rate (r)	10%	10%	Pharma WACC midpoint
α MA (Δ Rev)	0.30	0.30	Evidence-based; Table 3 range
OverlapAdj	15%	25%	Higher: more co-producing functions
PV(BenefitsMA)	\$73.5M	~\$83M	Eq. 1a
PV(CostMA)	\$68.2M	\$68.2M	Eq. 1b
Positive ROI (BCR)	1.08×	~ 1.22×	Eq. 1c
Net ROI (BCR – 1)	+ 0.08	+ 0.22	
Weighted β MA	0.50	0.55	Residual risk more human-dependent
PV(Gross Expected Losses, 5 year)	\$50M (\$35–78M)	~\$47M	Eq. 2a before β MA; AI reduces P(Loss) ~ 15%
PV(β MA-adjusted Losses, 5 year)	\$25M	~\$27M	Eq. 2a
PV(Foregone MA Budget, 5 year)	\$68.2M	\$68.2M	Eq. 2b (matches Eq. 1b)
Reverse ROI (gross)	0.73×	~ 0.69×	Eq. 2c
Reverse ROI (βMA-adjusted)	0.37×	~ 0.40×	Eq. 2c
Value map position (Fig. 2)	Point A	Point B	Above breakeven on Positive ROI; Reverse ROI stable
Probability stage (Box 2)	Stage 1	Stage 1	Baseline industry frequencies
<p><i>Positive ROI (BCR) exceeds 1× under evidence-based parameters (αMA = 0.30). Under conservative assumptions (αMA = 0.25, BCR = 0.87×), see ESM File S3. AI-era estimates reflect plausible assumptions about output multiplication at constant cost; they are illustrative, not validated. Benchmark inputs sourced from Table 4 Panel A. Gross Reverse ROI represents total enterprise risk exposure; βMA-adjusted represents the MA-preventable portion</i></p>			

3. HOW AI MODIFIES THE ROI

3.1 THE COST DENOMINATOR: REALLOCATION RATHER THAN REDUCTION

AI adoption in MA does not materially reduce total function cost.[3] Increased output volume requires proportionally greater expert review capacity, and new cost lines emerge: AI platform licences, validation infrastructure, and governance overhead. FTE profiles shift (fewer staff perform manual tasks, more serve as AI-literate medical scientists and senior reviewers) but aggregate cost remains broadly stable.

Under a representative scenario, a pre-AI MA function of 60 FTEs at US\$18 million per year transitions to 55 FTEs plus US\$2–3 million in AI tools and infrastructure, yielding a comparable annual cost of approximately US\$18 million. The PV(CostMA) denominator in Equations 1c and 2c remains approximately US\$68.2M over five years at a 10% discount rate. Any improvement in ROI must therefore come from the numerator.

3.2 THE BENEFIT NUMERATOR: OUTPUT MULTIPLICATION AT CONSTANT COST

AI increases what MA produces for the same investment across its principal activities (Table 7).

Medical writing and publications. AI-assisted drafting enables higher publication output, faster turnaround on evidence summaries, and broader congress presence from the same editorial team. The resulting gains affect CA (cost avoided through faster medical information responses and fewer compliance gaps from delayed answers) and SOV (more evidence assets available at key decision gates).

Evidence generation. AI-accelerated real-world evidence analysis compresses timelines for post-market studies, supports faster label-expansion dossiers, and increases the volume of evidence packages for health technology assessment submissions. This directly affects $\Delta rNPV$: more evidence generated faster de-risks pipeline assets and advances the revenue they generate.

Medical information. AI-enabled triage and response drafting reduce response times while maintaining accuracy under mandatory medical review[3, 4] lowering the probability of compliance breaches (a CA component).

MSL interactions and field insights. AI-augmented preparation and structured insight-capture systems improve the quality and traceability of the $\alpha MA \times \Delta \text{Revenue}$ component (the pathway from scientific engagement to downstream treatment adoption).

Medical education and scientific communications. AI-personalised content extends MA's reach across geographies and stakeholder segments without proportional FTE growth, generating new strategic options (SOV).

Estimated magnitude. If AI increases the Positive ROI numerator by approximately 10–15% through cumulative gains across these activities while the denominator remains constant, PV(BenefitsMA) rises from approximately US\$74M (pre-AI) to approximately US\$84M. This is partially offset by a higher OverlapAdj (increasing from 15% to 20% as more functions contribute to AI-augmented outcomes). The net result: Positive ROI (BCR) improves from approximately 1.08× to approximately 1.22×.

3.3 THE REVERSE ROI: CONCENTRATION OF HUMAN-DEPENDENT RISK

On the risk-prevention side, AI modifies loss probabilities. AI-augmented literature surveillance reduces the probability of missing safety-relevant publications. AI-assisted regulatory document preparation lowers submission delay risk. AI-enabled medical information triage reduces compliance exposure.

At the same time, AI introduces new risk categories. AI systems in medical contexts exhibit variable error rates depending on governance architecture; systems with retrieval-augmented generation and mandatory human oversight achieve substantially lower error rates than unguided implementations.[3] The FDA has emphasised that AI outputs intended to support regulatory decision-making require credibility assessment frameworks including human validation.[4, 5] AI-generated evidence or communications released without adequate medical review could result in regulatory findings, reputational harm, or patient safety concerns (risks with no pre-AI equivalent).

The net effect on β MA runs against expectations. AI generally reduces the probability of routine adverse events, but the residual risk (the risk AI cannot mitigate without human oversight) concentrates in medical judgement: signal escalation decisions, evidence strategy prioritisation, and the scientific credibility that sustains regulator and payer trust. β MA for these residual categories may therefore increase from 0.50 to 0.55–0.60 in an AI-augmented environment, even as the total risk pool decreases.

3.4 THE MEASUREMENT IMPERATIVE

The analysis above points to a structural concern. AI amplifies MA output and the benefit numerator grows, but this improvement is invisible without a financial framework to capture it. MA continues to report the same activity-based metrics it used before AI adoption, even as the value those activities generate has materially increased. The function produces more, but in the absence of a financial framework, the return on AI investment within MA cannot be demonstrated

MAVI addresses this through governed α MA and β MA coefficients, Box 1 documentation requirements, and cross-functional calibration panels. These provide the measurement architecture that converts AI-amplified output into a quantified financial case for continued MA investment.

4. ILLUSTRATIVE APPLICATION

This scenario demonstrates framework mechanics, not validated estimates. All parameters are derived from published benchmarks classified by credibility (Table 4, Panel A).[18–25] Low-credibility

benchmarks are flagged and should not inform investment decisions.

4.1 COMPANY PROFILE

Mid-size pharmaceutical company, US\$1 billion portfolio revenue, three marketed products, two label-expansion candidates. $T = 5$ years, $r = 10\%$. Year-by-year calculations are provided in ESM File S1.

4.2 PRE-AI BASELINE

Annual MA investment: US\$18M (60 FTEs, no AI tools). $PV(\text{CostMA}) = \text{US\$68.2M}$. With evidence-based parameters ($\alpha\text{MA} = 0.30$, reflecting documented MA contribution to evidence-mediated adoption; CA including regulatory query avoidance; $\text{OverlapAdj} = 15\%$), $PV(\text{BenefitsMA}) = \text{US\$74M}$. Positive ROI (BCR) = $1.08\times$ (Net ROI = $+0.08$). $PV(\text{Gross expected losses}) = \text{US\$50M}$ (\$35–78M range). Weighted $\beta\text{MA} = 0.50$. $PV(\beta\text{MA-adjusted losses}) = \text{US\$25M}$. Reverse ROI ($\beta\text{MA-adjusted}$) = $0.37\times$; Reverse ROI (gross) = $0.73\times$. Value map position: above breakeven on Positive ROI; below breakeven on Reverse ROI (Fig. 2, Point A).

4.3 AI-ERA SCENARIO

Annual MA investment: US\$18M (55 FTEs + US\$2.5M AI tools and infrastructure). $PV(\text{CostMA}) = \text{US\$68.2M}$ (unchanged). AI-augmented benefits: $\Delta r\text{NPV} + 30\%$ (accelerated evidence generation and additional label-expansion dossiers); CA + 15% (faster medical information turnaround, fewer protocol amendments through AI-assisted design); SOV doubles (AI-enabled strategic options including adaptive trial designs and predictive analytics); $\alpha\text{MA} \times \Delta\text{Rev} + 10\%$ (AI-augmented MSL engagement). OverlapAdj increases from 15% to 20%. $PV(\text{BenefitsMA}) \approx \text{US\$84M}$. Positive ROI (BCR) $\approx 1.22\times$ (Net ROI $\approx +0.22$).

Reverse ROI: $P(\text{Loss})$ decreases approximately 15% for routine surveillance categories; βMA increases modestly from 0.50 to 0.60 for residual risk categories. $PV(\beta\text{MA-adjusted losses}) \approx \text{US\$27M}$. Reverse ROI ($\beta\text{MA-adjusted}$) $\approx 0.40\times$. The Reverse ROI remains broadly stable, confirming that AI's primary impact is on value creation rather than risk prevention. Value map position: Positive ROI increases from $1.08\times$ to $1.22\times$ while Reverse ROI moves from $0.37\times$ to $0.40\times$ (Fig. 2, Point B).

4.4 INTERPRETATION

The illustrative scenario demonstrates three properties of the framework. First, the result is sensitive to attribution governance: with evidence-based parameters ($\alpha\text{MA} = 0.30$), Positive ROI exceeds breakeven (Fig. 2, Point A); under conservative assumptions ($\alpha\text{MA} = 0.25$, ESM File S3), it does not. The difference is measurement calibration, not MA performance. Second, the Reverse ROI dimension reveals a contribution that single-dimension analysis would miss: MA prevents expected enterprise losses worth a material fraction of its own budget, providing a risk-governance case that is invisible without two-dimensional measurement. Third, AI amplifies the Positive ROI through output multiplication at constant cost, while the Reverse ROI remains broadly stable (Fig. 2, arrow from Point A to Point B), a shift that is quantifiable only because the framework captures both dimensions."

This addresses a longstanding perception that MA's ROI is inherently unmeasurable. MAVI challenges this by applying standard corporate finance methodology, discounted cash flow, real options, probability-weighted loss estimation, to MA's specific value channels. The illustrative results suggest that the difficulty has not been that MA lacks ROI, but that it has lacked a framework for quantifying it. ESM File S3 presents a stress test using conservative parameters ($\alpha_{MA} = 0.25$, $BCR = 0.87\times$), demonstrating that even when Positive ROI falls below breakeven, the Reverse ROI dimension sustains the investment case.

These figures are illustrative and should not be treated as validated estimates. The underlying organisational question remains whether the enterprise is prepared to accept the unmitigated downside exposure that would follow from materially reducing MA capability. Events such as product recalls (US\$100M–US\$1B+)²⁴ may be low-probability but can be existential for mid-size companies.

A further consideration is progressive deskilling. As AI assumes routine tasks, junior MA professionals have fewer opportunities to develop domain expertise, potentially weakening the human oversight layer on which β_{MA} depends.

5. IMPLICATIONS AND PATH FORWARD

5.1 MAVI IN THE AI ERA

The analysis presented here suggests two conclusions. First, the financial case for MA is sensitive to measurement approach: when a structured framework is applied with governed attribution, the result differs materially from what activity-based reporting alone would suggest. Second, AI modifies the Positive ROI through output multiplication at approximately constant cost, while the risk-governance dimension remains stable, but this effect is quantifiable only with a framework that captures both dimensions. MAVI provides that framework. In a pre-AI environment, it offers a structured basis for MA investment discussions. In an AI-augmented environment, it enables organisations to assess whether AI adoption is generating a measurable return

Zdon et al. characterised MA as a strategic asset in launch execution, corporate reputation, and innovation.^[26] MAVI offers a quantitative approach to evaluating that characterisation, by enabling organisations to assess MA's contribution on both value creation and risk prevention within a single measurement architecture.

MAVI is not a health technology assessment framework. It draws on corporate finance concepts (NPV, real options, attribution) and is intended for senior leadership and finance decision-makers rather than reimbursement authorities.

The structural challenge MAVI addresses is not unique to MA. Any knowledge-intensive function that co-creates value across organisational boundaries (regulatory affairs, quality assurance, health economics, corporate affairs) faces analogous measurement difficulties that AI is likely to amplify. The two-

dimensional approach (positive return plus risk prevention) and the attribution governance architecture presented here may serve as a template for the financial evaluation of such functions more broadly.

5.2 COMPLIANCE BOUNDARIES

The following are structural requirements: (i) only non-promotional activities are eligible for MAVI quantification; (ii) promotional activities are excluded; (iii) calibration panels for α MA and β MA must include compliance representation; (iv) MAVI should not serve as a basis for MA personnel compensation linked to revenue outcomes; (v) revenue modelling should be evidence-mediated. AI-generated outputs used within MAVI quantification require human validation before being counted as MA-attributable.

5.3 LIMITATIONS AND NEXT STEPS

The proposed α MA and β MA ranges are expert-informed rather than empirically derived. Prospective calibration through cross-functional Delphi panels would strengthen the evidence base. Several benchmark inputs rely on heterogeneous sources of variable quality (Table 4, Panel A). The framework has not been prospectively validated and does not currently include patient outcomes as a direct value dimension.

Three AI-era priorities emerge. First, organisations should track how AI adoption changes α MA and β MA over time through longitudinal within-company calibration. Second, human-AI attribution protocols are needed: when AI and a medical scientist together produce an evidence package that supports a label expansion, the attribution must be governed and documented. Third, industry collaboration to develop AI-adjusted parameter libraries would reduce adoption burden and improve comparability.

A phased implementation programme, beginning with cost-avoided tracking, then adding Δ rNPV and Reverse ROI, and subsequently integrating AI-adjusted parameters, may better match organisational readiness than simultaneous deployment

6. CONCLUSION

MAVI provides a structured financial framework for quantifying the return on investment of Medical Affairs across two dimensions: value creation and risk prevention. Applied with evidence-based parameters, it reveals a Positive ROI above breakeven before AI adoption and demonstrates that AI further amplifies this return through output multiplication at approximately constant cost, while the risk-governance dimension remains stable. The framework addresses a measurement gap that has left MA unable to articulate its financial contribution in terms comparable to those used by R&D and Commercial functions. As AI reshapes pharmaceutical operations, the need for such a framework extends beyond MA to any knowledge-intensive function whose value is co-created, diffuse, and difficult to attribute. Empirical calibration through prospective, cross-functional implementation is the essential next step.

Declarations

Author contributions: G.B. Conceptualization, Methodology, Literature Synthesis, Writing Original Draft, Implementation Science Integration, MAVI Framework Development; T.B. Literature Synthesis, Framework Development, Review & Editing; All authors approved the final manuscript and accept responsibility for its content.

Conflicts of interest: G.B. is employed by Helsinn Healthcare SA, Switzerland; T.B. is employed by Miltenyi Biomedicine, Germany. The views expressed are those of the authors and do not necessarily represent the official positions of their affiliated institutions.

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Data Availability: This article is based on published literature, publicly available regulatory guidance, and expert synthesis. No original data were generated. The year-by-year present-value workbook is provided as ESM File S1. The literature research strategy is provided as ESM File S2.

Ethics and AI Use Statement: This article does not involve human participants or patient data. Generative AI tools were used to assist with literature research, reference formatting and structural editing (Claude, Anthropic). Figure 1, 2 and Supplementary Figure 1 were generated programmatically using Python (matplotlib). All AI-generated content was critically reviewed, verified and substantially modified by the authors. All citations were manually validated for accuracy through database searches and DOI verification. The authors accept full responsibility for the accuracy, scientific integrity, and intellectual content of this work..

References

1. Shah B, Adabala Viswa C, Zurkiya D, Leydon E, Bleys J. Generative AI in the pharmaceutical industry: moving from hype to reality. McKinsey & Company; 2024 Jan 9. Available from: <https://www.mckinsey.com/industries/life-sciences/our-insights/generative-ai-in-the-pharmaceutical-industry-moving-from-hype-to-reality>. Accessed 2026 Mar.
2. Liu Q, Huang R, Hsieh J, et al. Landscape analysis of the application of artificial intelligence and machine learning in regulatory submissions for drug development from 2016 to 2021. Clin Pharmacol Ther. 2023;113(4):771–4. 10.1002/cpt.2668.
3. Bate A, Hobbiger SF. Artificial intelligence, real-world automation and the safety of medicines. Drug Saf. 2021;44(2):125–32. 10.1007/s40264-020-01001-7.
4. US Food and Drug Administration. Using artificial intelligence & machine learning in the development of drug and biological products: discussion paper. Silver Spring (MD): FDA; 2023 May (revised 2025 Feb). Available from: <https://www.fda.gov/media/167973/download>. Accessed 2026 Mar.

5. US Food and Drug Administration. Considerations for the use of artificial intelligence to support regulatory decision-making for drug and biological products: draft guidance for industry. Silver Spring (MD): FDA; 2025 Jan. Federal Register docket FDA-2024-D-4689. Available from: <https://www.federalregister.gov/documents/2025/01/07/2024-31542/considerations-for-the-use-of-artificial-intelligence-to-support-regulatory-decision-making-for-drug>. Accessed 2026 Mar.
6. Darino L, Knepp A, Mills N, Tinkoff D. How pharma can accelerate business impact from advanced analytics. McKinsey & Company; 2018 Jan 8. Available from: <https://www.mckinsey.com/industries/life-sciences/our-insights/how-pharma-can-accelerate-business-impact-from-advanced-analytics>. Accessed 2026 Mar.
7. Algazy J, Garcia A, Ryan S, Westra A, Zemp A. A vision for medical affairs 2030: five priorities for patient impact. McKinsey & Company; 2023 Oct. Available from: <https://www.mckinsey.com/industries/life-sciences/our-insights/a-vision-for-medical-affairs-2030-five-priorities-for-patient-impact>. Accessed 2026 Mar.
8. Farrington AD, Frøstrup AG, Dahl P. The value and deliverables of medical affairs: affiliate perspectives and future expectations. *Pharmaceut Med*. 2023;37(6):417–24. 10.1007/s40290-023-00501-y.
9. Medical Affairs Professional Society (MAPS). Measuring value and impact in medical affairs: standards and guidance document. Golden (CO): MAPS. 2025. Available from: https://medicalaffairs.org/wp-content/uploads/2025/01/UPDATE_1.21.25-STRATEGY_Value-and-Impact-in-Medical-Affairs_SG-pwp.pdf. Accessed 2026 Mar.
10. Dyer S, Hyder C, Kraemer J. Challenges of key performance indicators and metrics for measuring Medical Science Liaison performance: insights from a global survey. *Pharmacy*. 2025;13(2):51. 10.3390/pharmacy13020051.
11. Jandhyala R. Development and validation of the Medical Affairs Pharmaceutical Physician Value (MAPPval) Instrument. *Pharmaceut Med*. 2022;36(1):47–57. 10.1007/s40290-021-00413-9.
12. Kaplan RS, Norton DP. The balanced scorecard: translating strategy into action. Boston (MA): Harvard Business School Press; 1996.
13. Kaplan RS, Norton DP. Strategy maps: converting intangible assets into tangible outcomes. Boston (MA): Harvard Business School Press; 2004.
14. Jandhyala R. Development of a definition for medical affairs using the Jandhyala method for observing consensus opinion among medical affairs pharmaceutical physicians. *Front Pharmacol*. 2022;13:842431. 10.3389/fphar.2022.842431.
15. Jandhyala R. Development, validation and implementation of the medical affairs pharmaceutical physician work-related quality of life instrument. *Curr Med Res Opin*. 2023;39(12):1567–74. 10.1080/03007995.2023.2174747.
16. Saleem M, Cesario L, Wilcox L, et al. Evaluating metrics applied to the Medical Science Liaison (MSL) role: a survey-based study of Canadian MSL leaders. *Ther Innov Regul Sci*. 2021;55(5):954–65. 10.1007/s43441-021-00291-y.

17. Lucid Group. Share of Scientific Voice (SoSV): methodology and benchmarking. White Paper. Published 2023. Available from: <https://wearelucidgroup.com/white-papers/medical-affairs-kpis>. Accessed 2026 Mar.
18. IQVIA. In pursuit of Medical Launch Excellence: lessons for medical affairs from IQVIA's Launch Excellence research (White paper). Durham (NC): IQVIA; 2023 Nov 30. Available from: <https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/in-pursuit-of-medical-launch-excellence.pdf>. Accessed 2026 Mar.
19. Getz KA, Stergiopoulos S, Marlborough M, Whitehill J, Curran M, Kaitin KI. Quantifying the magnitude and cost of collecting extraneous protocol data. *Am J Ther*. 2015;22(2):117–24. 10.1097/MJT.0b013e31826fc4aa.
20. Hay M, Thomas DW, Craighead JL, Economides C, Rosenthal J. Clinical development success rates for investigational drugs. *Nat Biotechnol*. 2014;32(1):40–51. 10.1038/nbt.2786.
21. Wong CH, Siah KW, Lo AW. Estimation of clinical trial success rates and related parameters. *Biostatistics*. 2019;20(2):273–86. 10.1093/biostatistics/kxx069.
22. Smith ZP, DiMasi JA, Getz KA. New estimates on the cost of a delay day in drug development. *Ther Innov Regul Sci*. 2024;58(5):855–62. 10.1007/s43441-024-00667-w.
23. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: new estimates of R&D costs. *J Health Econ*. 2016;47:20–33. 10.1016/j.jhealeco.2016.01.012.
24. Associated Press. Philips will pay \$1.1 billion to resolve US lawsuits over breathing machines that expel debris. *AP News*. 2024 Apr 29. Available from: <https://apnews.com/article/philips-sleep-apnea-settlement-recall-safety-fc5cc1509656645d7f5679e0f1b34b85>. Accessed 2026 Mar.
25. European Parliament and of the Council. Regulation (EU) 2017/745 of 5 April 2017 on medical devices. *OJ L 117*, 5.5.2017, pp. 1–175. <https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng>
26. Zdon J, Chatgilaou GJ, Henderson D, et al. How can general managers best leverage medical affairs now and in the future? *Pharmaceut Med*. 2024;38(4):277–90. 10.1007/s40290-024-00528-9.

Figures

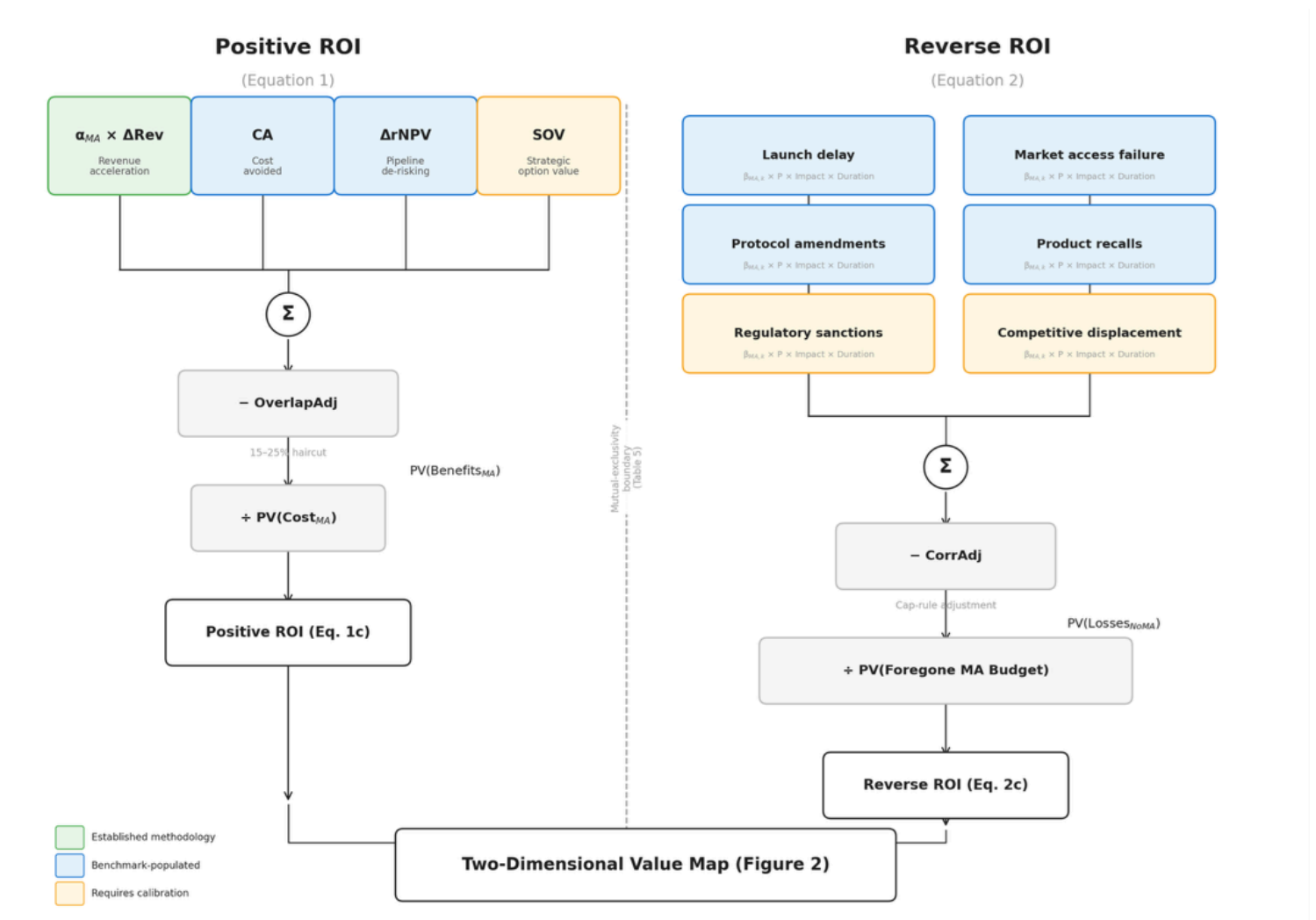


Figure 1

Conceptual overview of MAVI architecture.

The left panel shows the Positive ROI pathway (Equation 1): four benefit components ($\alpha_{MA} \times \Delta Rev$, CA, $\Delta rNPV$, SOV) are summed, reduced by an overlap adjustment (OverlapAdj), discounted to present value, and divided by PV(Cost_{MA}) to yield the benefit–cost ratio. The right panel shows the Reverse ROI pathway (Equation 2): six loss categories, each weighted by $\beta_{MA,k} \times P(Loss) \times Impact \times Duration$, are summed, reduced by a correlation adjustment (CorrAdj), discounted, and divided by PV(Foregone MA Budget). Colour coding indicates data maturity: green = established methodology; blue = benchmark-populated; amber = requires calibration. A mutual-exclusivity boundary (Table 5) ensures no value stream is counted in both panels. Both outputs converge in the two-dimensional value map (Figure 2). MAVI, Medical Affairs Value Index; PV, present value; BCR, benefit–cost ratio; MA, Medical Affairs.

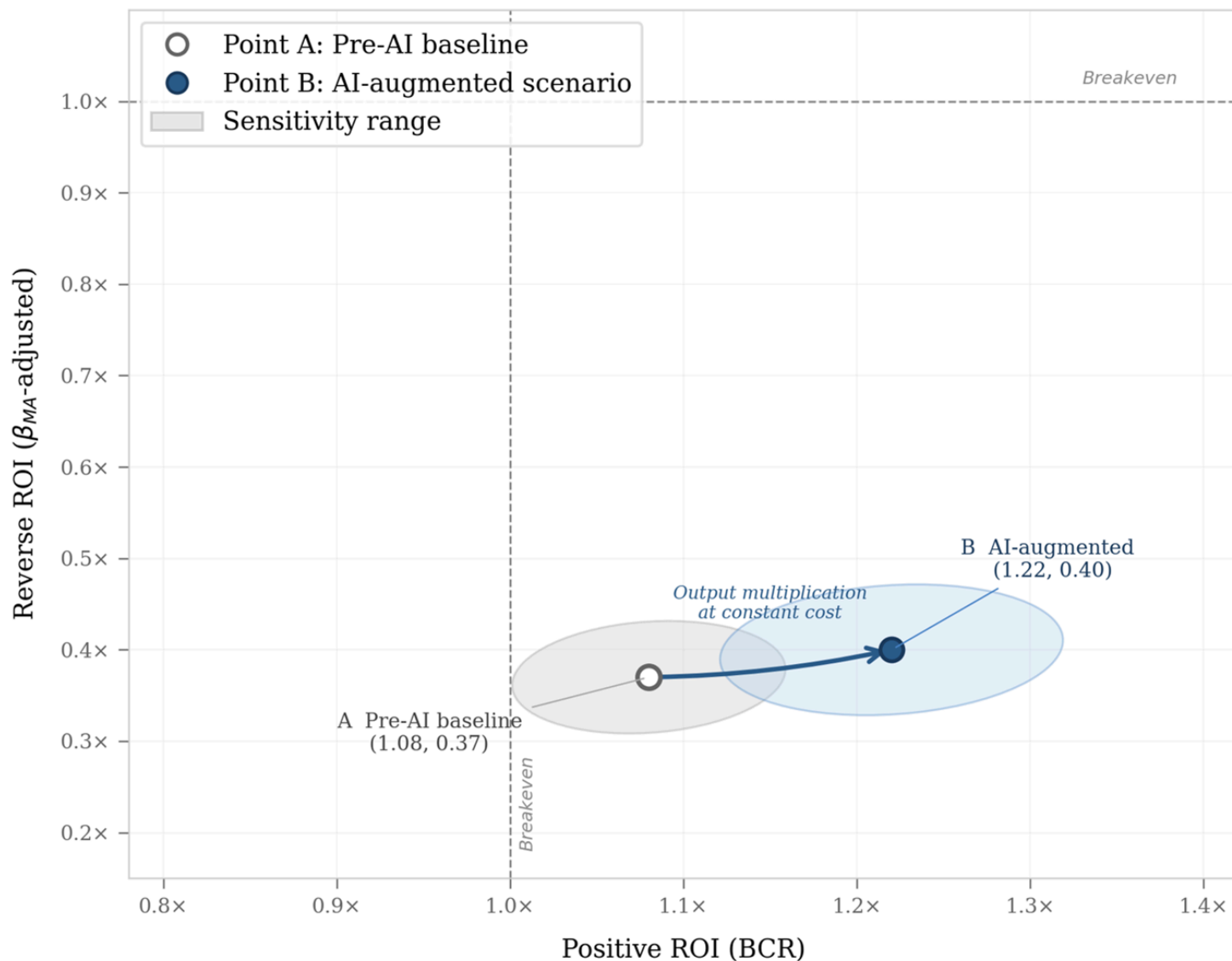


Figure 2

MAVI value map: pre-AI and AI-augmented scenarios

Positive ROI (BCR) is plotted on the horizontal axis and Reverse ROI (β_{MA} -adjusted) on the vertical axis. Point A represents the pre-AI baseline under evidence-based parameters ($\alpha_{MA} = 0.30$; BCR = 1.08x; Reverse ROI = 0.37x). Point B represents the AI-augmented scenario at approximately constant total MA cost (BCR = 1.22x; Reverse ROI = 0.40x). The arrow indicates the shift achieved through AI-driven output multiplication. Dashed lines at 1.0x indicate breakeven on each dimension. Shaded ellipses represent sensitivity ranges under parameter variation. Full year-by-year calculations are provided in ESM File S1. A conservative-assumptions variant of the value map is provided in ESM File S3 (Figure S1). BCR, benefit–cost ratio; MA, Medical Affairs.

Supplementary Files

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