Contribution
Analysis (CA)

Theory of
Change (ToC)

White Paper:

Exploring Novel Ways
to Measure the Impact
of Medical Affairs

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As explored in our December 2024 article, Medical Affairs has taken on an increasingly wide-ranging remit over recent years, which has brought with it an increasing level of accountability; more and more, the focus is not what Medical Affairs does, but what difference it makes.

Yet it can be hard to quantify the impact of Medical Affairs. Impact is often underrecognized due to the complexity involved in attributing long-term, multi-faceted outcomes to specific Medical activities.

In the article, we introduced two frameworks that have proven effective for helping assess impact in other industries where – as with Medical Affairs – outcomes are long-term, multi-factorial, and difficult to isolate: Theory of Change (ToC), and Contribution Analysis (CA). Here, we take a closer look at these frameworks and their potential application to the world of Medical Affairs.

This white paper will help Medical Affairs teams move beyond reporting on process-oriented metrics, to more meaningfully reporting on the impact they deliver.

A deeper dive into ToC and CA

Organizations outside the pharmaceutical industry – particularly in international development and public health – have long used ToC and CA to help measure impact in complex environments.

Theory of Change

At its core, ToC is a planning and evaluation framework that maps the causal pathways from activities to long-term outcomes. It provides a structured way to articulate how specific interventions are expected to achieve desired changes, while identifying the assumptions and external factors that underpin these pathways[1].

Key components of ToC include (Figure 1):

1. **Inputs:** Resources and investments (e.g., funding, expertise, tools).
2. **Activities:** Actions undertaken (e.g., medical education sessions, advisory boards).
3. **Outputs:** Immediate results (e.g., HCPs trained, educational content volume and level of engagement generated).
4. **Outcomes:** Intermediate changes (e.g., increased awareness, changes in prescribing behavior).
5. **Impact:** Long-term goals (e.g., improved survival rates, reduced disease burden).
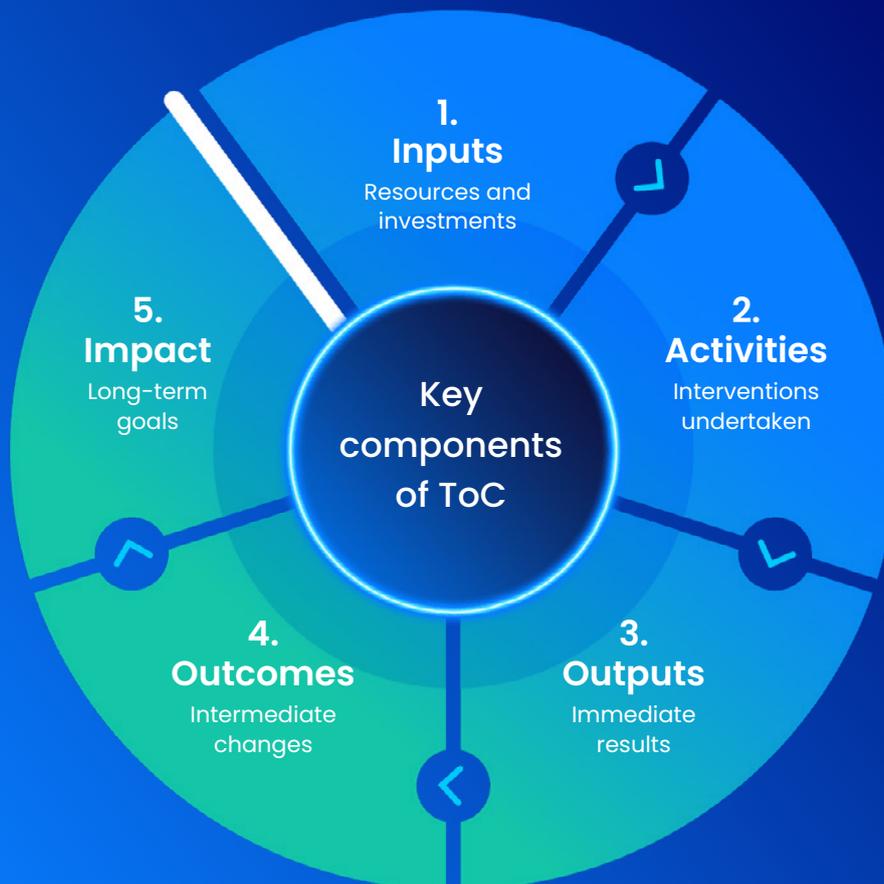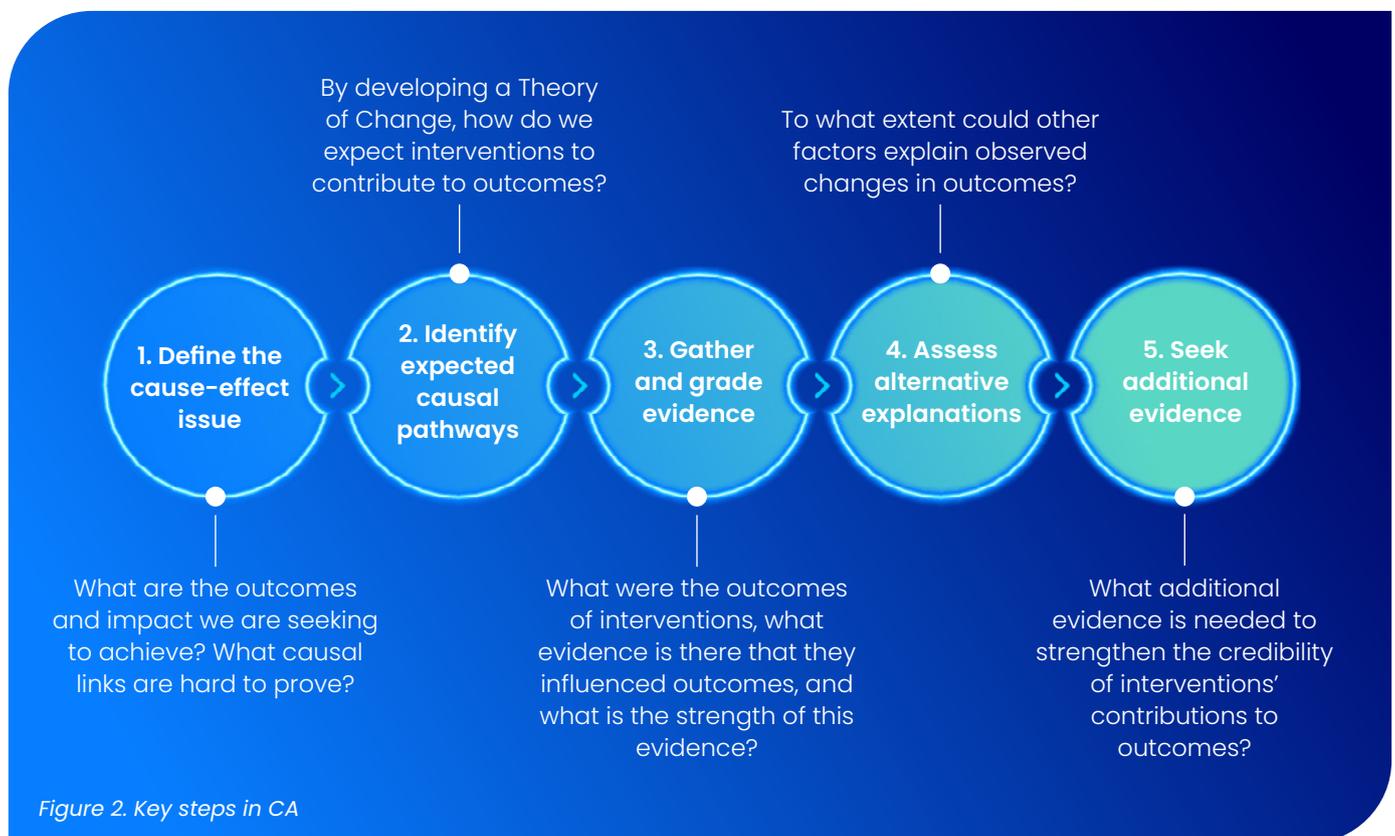

Figure 1. Key components of ToC

Contribution Analysis

While ToC is primarily a planning tool, CA focuses on evaluation. It is designed to assess whether and to what extent an intervention has contributed to observed outcomes, particularly in settings where multiple factors are at play.

A simplified view of the key steps in CA is as follows (Figure 2)[2]:

1. **Define** the cause–effect issue to be addressed.
2. **Develop a ToC** as a baseline for identifying expected causal pathways.
3. **Gather evidence** on implementation and outcomes, grading the evidence to assess the strength of the intervention's contribution to outcomes.
4. **Assess alternative explanations** to determine whether other factors could explain observed changes.
5. **Seek additional evidence as needed** to achieve the required credibility of, and confidence in, the intervention's contribution to outcomes.

By developing a Theory of Change, how do we expect interventions to contribute to outcomes?

To what extent could other factors explain observed changes in outcomes?

1. Define the cause-effect issue
2. Identify expected causal pathways
3. Gather and grade evidence
4. Assess alternative explanations
5. Seek additional evidence

What are the outcomes and impact we are seeking to achieve? What causal links are hard to prove?

What were the outcomes of interventions, what evidence is there that they influenced outcomes, and what is the strength of this evidence?

What additional evidence is needed to strengthen the credibility of interventions' contributions to outcomes?

Figure 2. Key steps in CA

Grading evidence in CA

A key element of CA involves systematically grading the strength of evidence supporting the intervention's contribution[3]. This grading assesses:

- **Data consistency:** Does the evidence align with the ToC?
- **Causal links**: Is there a credible connection between the intervention and the outcomes?
- **Counterfactual analysis:** Have alternative explanations been sufficiently ruled out?

An example of a grading framework is as follows:

- **Strong evidence:** Multiple data sources corroborate the intervention's impact, and alternative explanations are implausible.
- **Moderate evidence:** Evidence supports the intervention's role, but alternative explanations are partially credible.
- **Weak evidence**: Data are inconclusive, or other factors could explain the results.

Applying the frameworks to Medical Affairs: An illustrative example

Let us consider a hypothetical example in oncology – a disease area characterized by rapid innovation and significant unmet needs. Imagine a Medical Affairs team tasked with improving patient outcomes in advanced non-small cell lung cancer (NSCLC), where treatment paradigms are shifting due to the advent of targeted therapies.

As a result of mapping the patient pathway and identifying unmet needs at each step, the team prioritizes a key unmet need to address in alignment with their broader Medical strategy: low adoption of biomarker testing among oncologists, which is crucial for identifying patients eligible for targeted treatments. They design a suite of initiatives aimed at addressing this gap, including:

Conducting educational workshops for oncologists on the importance of biomarker testing.

Developing materials to simplify test interpretation.

Partnering with pathology labs to streamline testing workflows.

The team targets these interventions to a specific region as a pilot program, aiming to roll them out more widely should they be assessed as making a meaningful contribution to achieving the desired outcomes.

Using ToC to link activities to intended outcomes

To help clearly articulate the rationale behind their planned interventions, the team maps the expected causal pathway from activities to outcomes and impact (Figure 3):

1. **Inputs:** Funding, expertise in oncology and diagnostics.
2. **Activities**: Workshops for oncologists, development of educational materials, lab partnerships.
3. **Outputs**: Oncologist attendance and engagement at workshops, reach of and engagement with educational materials, improved lab capabilities.
4. **Outcomes**
    Short-term: Increased oncologist awareness of biomarker testing.
    Medium-term: Higher rates of biomarker testing among patients; increase in appropriate use of targeted therapies.
5. **Impact:** Improved survival rates for NSCLC patients due to appropriate use of targeted therapies.

The ToC serves as a roadmap for identifying causal links and assumptions that must hold true to show a pathway from inputs to impact.
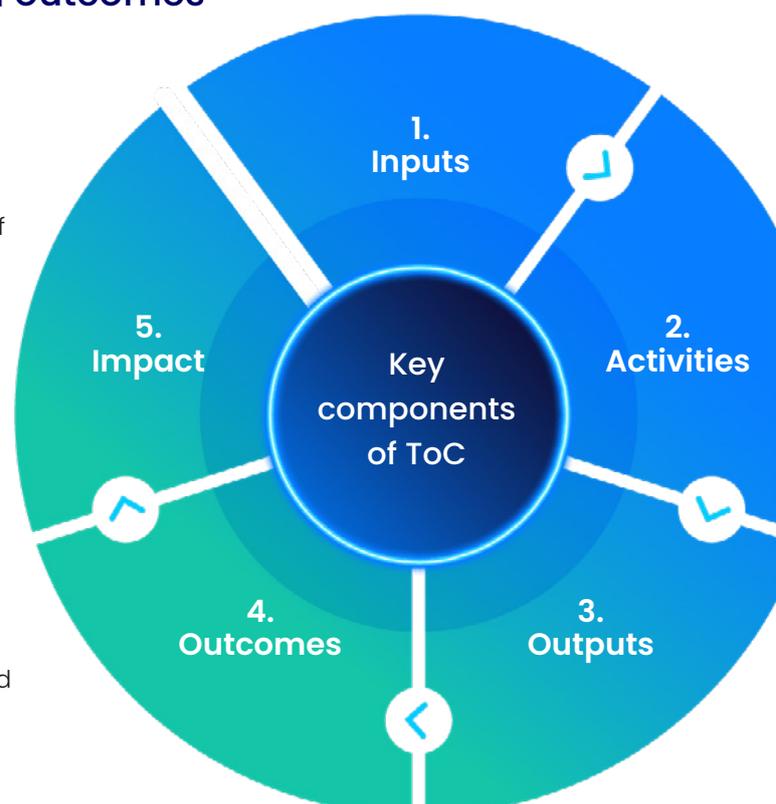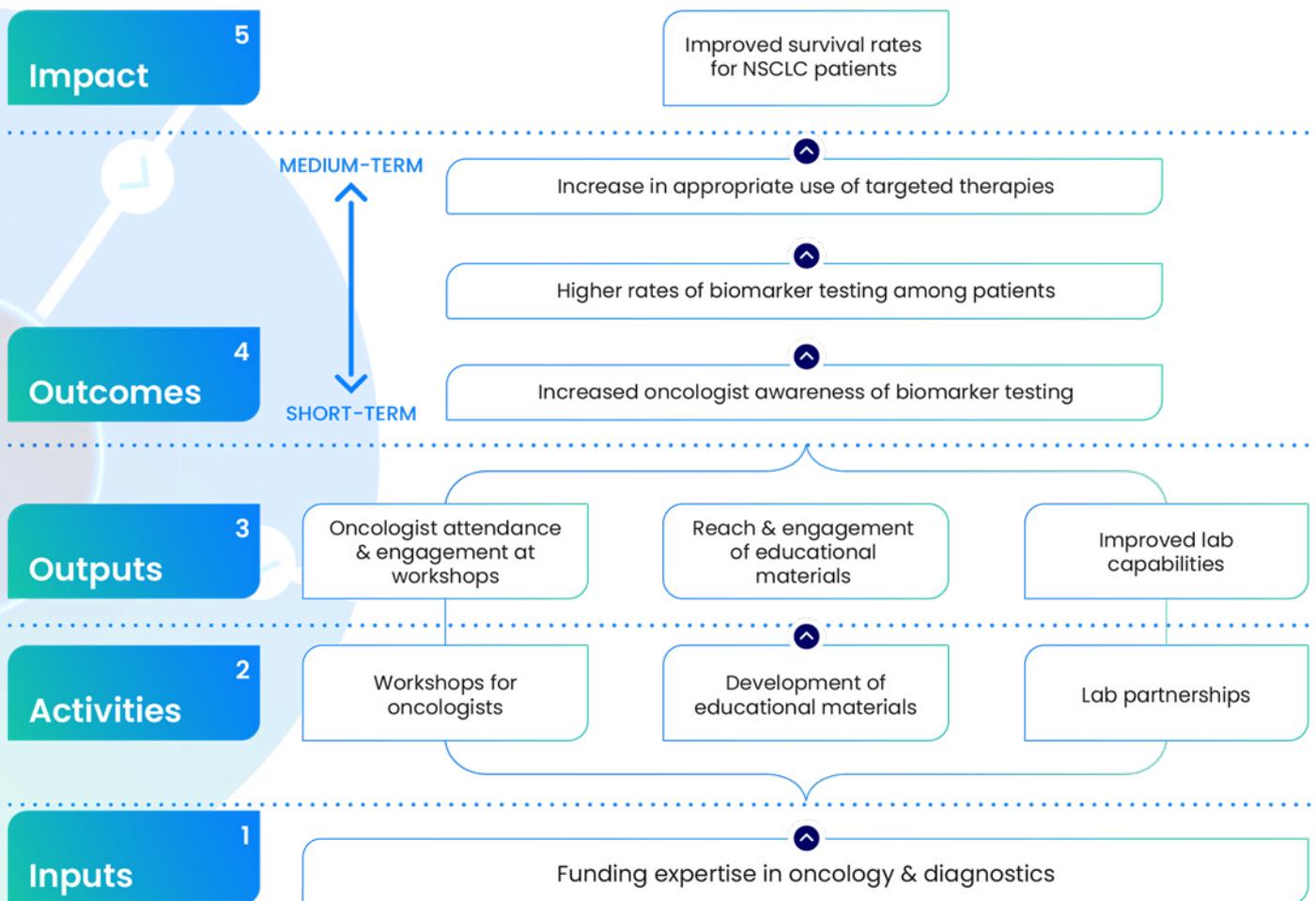
Figure 3. Summary of key ToC components

CA: Step-by-step application

A year later, the team evaluates their impact using CA as a framework.

Step 1: Define the cause-effect issue: The primary question is whether Medical Affairs activities – specifically workshops, educational materials, and lab partnerships – contributed to increased biomarker testing rates and improved NSCLC patient outcomes.

Step 2: Develop a ToC: The team uses their ToC as a framework to demonstrate the expected chain of causality from their activities up to the intended outcomes and impact (improved NSCLC patient outcomes).

Step 3: Gather evidence and grade its strength: The team collects data to evaluate the strength of each intervention's contribution:

- *Workshop impact:* Attendance records show that 70% of oncologists in the region participated. Post-workshop surveys indicate a 90% increase in self-reported confidence in ordering and interpreting biomarker tests.
- *Educational materials:* Distributed materials were accessed by 80% of oncologists in the region, with embedded feedback polls indicating 75% of these oncologists reported improved clarity in understanding biomarker reports.
- *Lab data:* 90% of partnering labs reported streamlining testing workflows. They also reported a 40% increase in biomarker testing rates over the last year, compared with a 15% increase in regions without lab partnerships.
- *Clinical behavior:* Real-world evidence indicates a 10% increase in use of targeted therapies requiring biomarker testing in the region.
- *Patient outcomes:* Real-world evidence indicates a 5% improvement in progression-free survival among NSCLC patients in the region.

The outcomes and impact evidence can be graded as follows:

| Evidence	Grading	Rationale
90% increase in self-reported confidence around biomarker testing from workshop attendees	STRONG	Feedback directly assessed workshops' influence on oncologists' confidence around utilizing biomarker tests, showing a direct causal link from intervention to outcome
75% of oncologists accessing content reported greater understanding of biomarker reports	STRONG	Feedback directly assessed the content's influence on confidence around utilizing biomarker tests, showing a direct causal link from intervention to outcome
40% increase in biomarker testing rates at partnering labs vs 15% increase in other regions	MODERATE	The comparison to labs outside of the intervention region suggests the increase in biomarker testing was at least partly attributable to the interventions, but there may have been other factors influencing outcomes (e.g., other educational initiatives, other partnership programs, regulatory incentives for oncologists to order testing)
10% increase in use of targeted therapies	MODERATE	There appears to be a causal path from the interventions to the outcome, but there may have been other influencing factors (e.g., new product approvals, access considerations, patient population characteristics and treatment eligibility, other educational initiatives)
5% improvement in PFS among NSCLC patients	WEAK–MODERATE	There appears to be a causal path from the interventions to the outcome, but there are a wide range of other potential influencing factors (e.g., interventions promoting earlier disease detection and diagnosis, population health considerations, earlier-line treatment selection)

Figure 4 summarizes the available evidence.
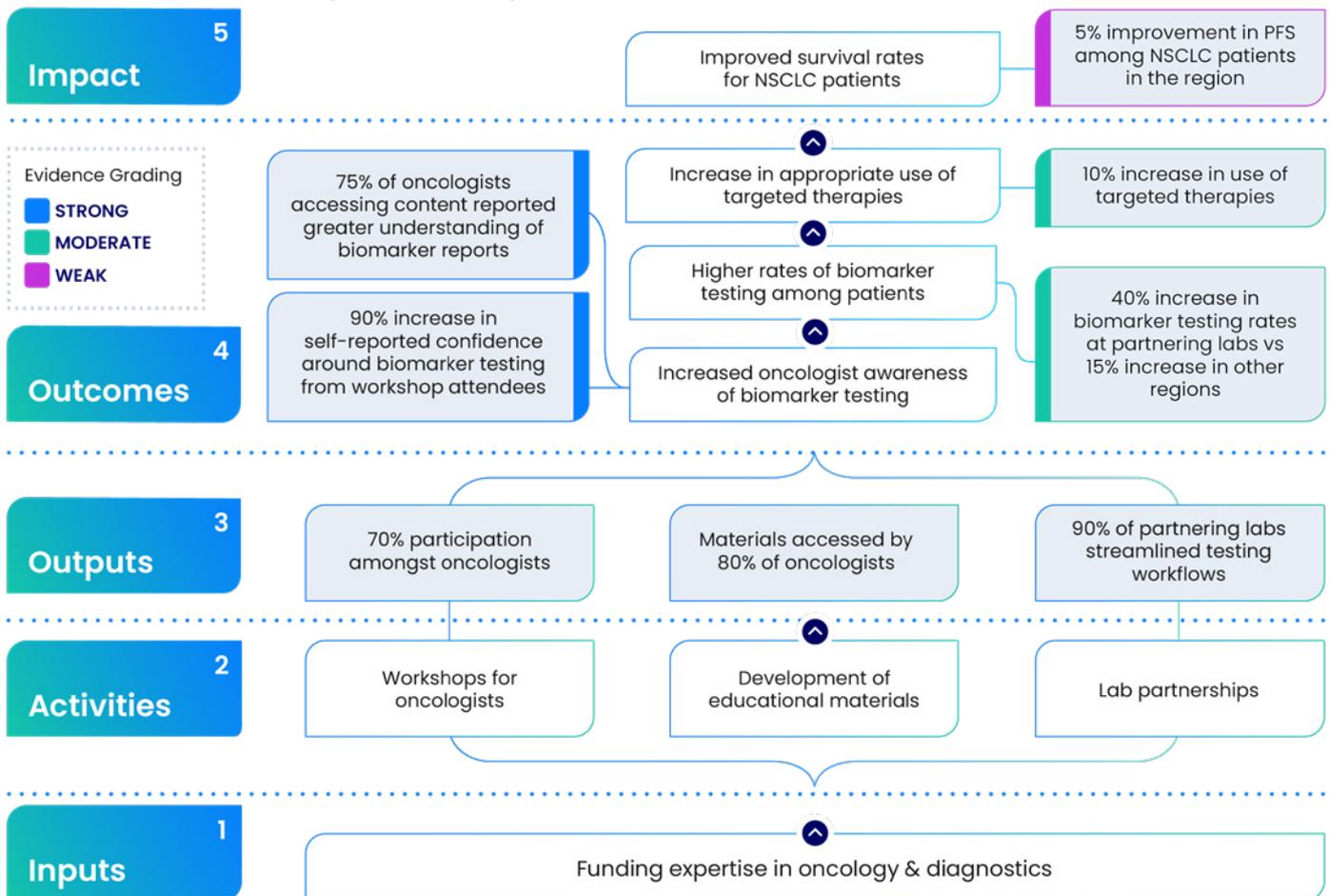
Figure 4. Graded evidence on intervention outcomes

Step 4: Assess alternative explanations: The team evaluates whether other factors could explain the observed changes:

- Regulatory changes incentivized biomarker testing; yet these were implemented uniformly across regions, while the largest increases were observed in the region where the Medical Affairs interventions occurred.
- Competing educational and lab partnership programs had limited overlap in geographic scope, reducing their potential influence.

Step 5: Seek additional evidence: To enhance credibility, the team conducts follow-up interviews with oncologists and lab staff to better understand decision-making drivers. The feedback confirms that workshops and educational tools were critical in increasing awareness and simplifying the implementation of biomarker testing, and that in turn, oncologists were reporting higher rates of use of targeted therapies due to their increased utilization of biomarker testing.

Findings

The team showed a contributory pathway from their interventions towards improved patient outcomes

Based on this systematic approach, the team concludes that their initiatives made a strong and plausible contribution to improved biomarker testing rates and an increase in appropriate use of targeted therapies, thereby showing a contributory pathway towards improved patient outcomes in the target region. This helps them secure further resource and investment to implement these interventions across other regions as part of next year's Medical plans.

Conclusion

By adopting these frameworks, Medical Affairs teams can demonstrate their value in a robust and credible manner

Medical Affairs teams are uniquely positioned to drive meaningful change in healthcare, but their impact often goes unmeasured or underrecognized. By adopting frameworks like ToC and CA, Medical Affairs can not only design more effective initiatives but also demonstrate their value in a robust and credible manner.

This approach is particularly valuable in high-stakes areas like oncology, where addressing unmet needs along the patient pathway can translate into life-changing improvements for patients. As the role of Medical Affairs continues to evolve, so too must our methods for measuring its success – moving beyond process-oriented metrics to a deeper understanding of impact.

Here at Prime, we help Medical Affairs teams demonstrate the impact of their initiatives, using learnings to optimize strategies and plans to drive meaningful change for HCPs and patients. We are continually exploring new approaches to impact measurement, so please do get in touch to explore this topic further.

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References

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