

# Companion Diagnostic Access Strategy

Mapping CDx reimbursement risk and building a strategic mitigation playbook across 17 European markets for a major global oncology alliance

*Latif Strategic Advisory · 2026*

## Latif Strategic Advisory Ltd

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Strategic Advisory · Market Access · Pricing · Policy

**17**

Markets

**8–9 wks**

Delivery Sprint

**>€100K**

Engagement Value

**Won**

Proposal Outcome

## THE SITUATION

A major global oncology alliance was preparing to launch a novel ADC asset in platinum-resistant ovarian cancer requiring a companion diagnostic to identify eligible patients.

The problem was systemic: across 17 European markets, CDx reimbursement pathways were fragmented, inconsistent, and in many cases untested for novel IHC-based diagnostics. Reliable funding could not be assumed to follow regulatory approval. Without early intervention, the alliance risked delayed patient identification, uneven access, and constrained launch sequencing — threats that were commercially material but poorly understood internally.

## THREE QUESTIONS THE ALLIANCE NEEDED TO ANSWER

### 01

#### **Where will CDx reimbursement fail at launch?**

Which markets face delays, insufficient coverage or no public funding pathway — and how severe is each gap?

### 02

#### **Which markets represent the greatest commercial risk?**

How do expected CDx timelines map against regulatory approval and launch sequencing priorities?

### 03

#### **What can the alliance actually do about it?**

Which mitigation strategies are deployable within launch timelines — and what is the trade-off between effort and impact?

# 01

## CDx Reimbursement Landscape & Gaps

- Map CDx funding pathways and key stakeholders across all markets
- Assess potential evolution of funding rules over 4-year launch window
- Identify markets where reimbursement is likely to be delayed or absent
- Validate with in-country P&MA experts across EU4 and select global markets

OUTPUT → Landscape overview  
+ funding gap assessment

# 02

## Market Categorization

- Co-create categorization framework with client team
- Segment markets by gap severity and feasibility to mitigate
- Host working session with extended alliance team
- Align on prioritization matrix as input to Phase 3

OUTPUT → Market priority matrix  
+ categorization framework

# 03

## Strategic Recommendations

- Develop mitigation options tailored to each market category
- Assess effort, timing and risk for each strategic option
- Build scalable above-asset playbook for future alliance assets
- Present final report to core and extended client teams

OUTPUT → Actionable playbook  
+ market-specific strategies



## Reimbursement Landscape

A comprehensive map of CDx funding pathways, key stakeholders, and reimbursement rules across all 17 European markets plus Israel — including projected evolution over the 4-year launch window.



## Market Prioritization Matrix

A 2x2 market segmentation framework categorizing each market by gap severity and feasibility to address, with clear guidance on which markets require proactive investment vs standard pathway.



## Strategic Mitigation Playbook

A suite of 7+ strategic options (manufacturer funding, bundling, patient programs, policy shaping) with assessment of timing, effort and risk for each — applicable to current and future alliance assets.

### WHAT MADE THIS WORK

Senior leadership on all strategic decisions

17-market expert network for local validation

Co-creation with client — not a report, a roadmap

## THE OUTCOME

The alliance used the output to sequence their EU launch approach, prioritize mitigation investment by market, and establish a reusable access framework scalable across their oncology pipeline.

### Risk Anticipated

CDx reimbursement gaps identified and categorized across all markets before regulatory approval — enabling proactive rather than reactive management.

### Decision Confidence

Alliance leadership entered launch sequencing discussions with a defensible, evidence-based playbook rather than fragmentary market-level assumptions.

### Scalable Framework

The above-asset playbook was designed for reuse across future pipeline assets — delivering lasting value beyond the immediate engagement.

## WHAT THIS DEMONSTRATES

- Senior strategic leadership across complex, multi-stakeholder engagements in EU oncology market access
- Ability to translate fragmented, ambiguous market landscapes into clear, decision-ready strategic frameworks
- Delivery model that blends primary expert research, internal validation, and co-created client outputs
- Track record of winning competitive mandates at major global pharma alliances on high-stakes launch-critical work