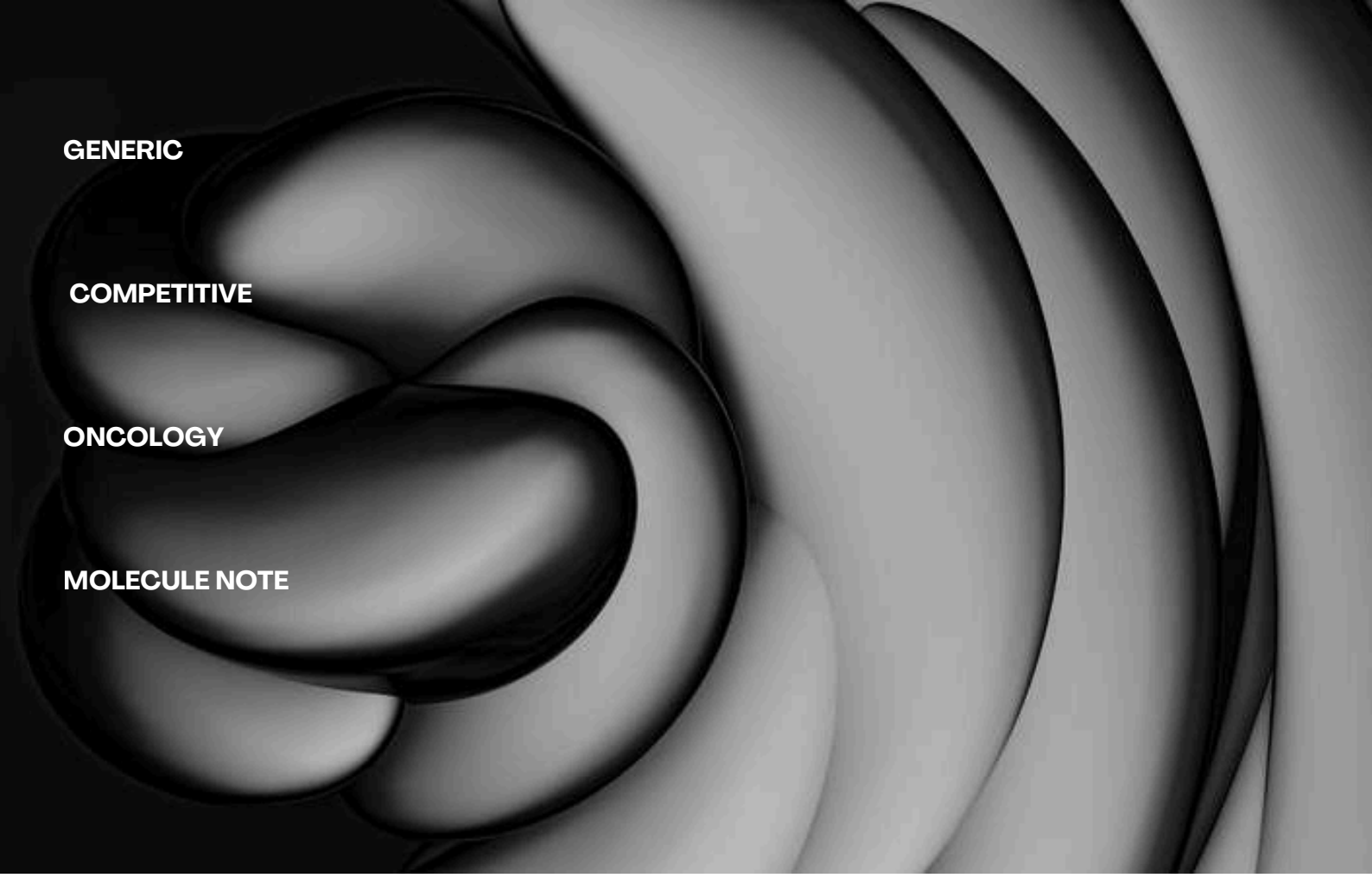


GENERIC

COMPETITIVE

ONCOLOGY

MOLECULE NOTE

For the originator defending leadership, prospective biosimilar challengers preparing lawful entry, and selective hospital or access players.

A PRODUCT CAN REACH THE HOSPITAL WHILE THE PATIENT REMAINS LOST BETWEEN DECISIONS

PEMBROLIZUMAB INTEGRATED COMPETITIVE MOLECULE PLAYBOOK FOR INDIA

INDITECH X INDIA X ONCOLOGY



Pembrolizumab

STRATEGIC POSITION	THE OPPORTUNITY
Originator leader	Defend institutional trust through verifiable access, supply and safe coordination after independent clinical selection.
Prospective biosimilar challenger	Build approval, evidence and service readiness now. Compete for product share only after lawful Indian approval and launch.
Selective access player	Solve a specific hospital, geography or pathway problem using lawfully supplied products; do not invent another pembrolizumab brand.

The competitive opening is the unfinished clinical pathway: a report awaiting interpretation, an unaffordable plan, an infusion booked before readiness, or a new symptom with no clear route back to oncology. A funded service earns credibility only when it helps the hospital close those gaps without steering treatment.

One verified marketed exact-molecule brand: Keytruda, MSD. No independently marketed pembrolizumab biosimilar or second brand was established in the public evidence reviewed through 3 November 2026. Development candidates are not current commercial alternatives. [1–7]

This market-facing note makes the same opportunity available to actual and prospective competing pembrolizumab product teams where legally relevant. It is not exclusive to one company. It does not assert that the note has already been distributed, accepted or implemented by any team.

EXECUTIVE COMMERCIAL THESIS

MAKE THE COMPLETED CARE DECISION THE UNIT OF COMPETITION

Recommendation: start with a narrow Biomarker to Treatment to Toxicity Review pathway in oncology hospitals that already have an accountable clinical response team. Extend it only after the hospital can demonstrate reliable handovers and acceptable workload. A broad engagement platform adds little if an abnormal result or urgent symptom still waits without an owner.

THE DISRUPTION

Traditional oncology promotion explains the molecule and its evidence. The proposed service helps a hospital execute its own decision: obtain the right report, resolve an access barrier, verify readiness and recognise deterioration. The commercial hypothesis is that dependable execution can earn institutional consideration. It is not a promise of more prescribing or longer treatment.

POSITION	WHAT CAN CHANGE NOW	WHAT MUST NOT CHANGE
Leader	Move from product familiarity to reliable institutional execution.	Clinical independence and fair procurement.
Prospective challenger	Prepare a credible evidence and hospital-readiness dossier.	No pre-approval promotion, substitution or advance prescribing commitment.
Selective access	Improve one measurable bottleneck in a reachable hospital network.	Support eligibility cannot depend on purchase, brand or prescriber volume.

THREE TESTS BEFORE INVESTMENT

Clinical test: can the pathway help the patient reach an appropriate oncology decision, including another therapy or no immunotherapy? Operating test: can the hospital respond to every escalated concern? Commercial test: can a lawful institutional benefit be measured separately from care, without patient-level sales tracking? Failure of the first two ends the investment case.

READING ROUTE	DECISION
Market and clinical reality Sections 02–09	What can lawfully compete and which tumour pathways are suitable?
Hospital service and education Sections 10–20	Who does the work, when, and under whose authority?
Competition and deployment Sections 21–24	How do the three positions differ in execution?
Governance and proof Sections 25–31	What evidence would justify continuing or stopping?

INDIA REGULATORY REALITY

CONCENTRATED TODAY DOES NOT MEAN UNCONTESTED TOMORROW

The defensible conclusion is narrow: Keytruda is the only independently marketed pembrolizumab brand verified for India in this review. A second approved and marketed exact-molecule product was not identified. This is an evidence-based market conclusion, not a guarantee that every regulatory transaction is immediately public. [1–5]

EVIDENCE CHECK	WHAT IT ESTABLISHES	LIMIT
MSD India product portal [1]	Keytruda is listed for Indian healthcare professionals.	The detailed product page is login-restricted; a full current Indian PI must be obtained for deployment.
CDSCO CT-18 list through September 2026 [2]	Pembrolizumab import and additional-indication records identify MSD. Includes the August 2026 perioperative head-and-neck indication.	The list is an approval summary, not a complete prescribing label.
CDSCO CT-21 list through September 2026 [3]	No pembrolizumab entry was found in the published manufacture-and-marketing list.	Absence from a periodic list alone cannot prove universal absence.
SUGAM query on 3 November [4]	Exact pembrolizumab product results identify MSD; combination-partner results are also returned.	Search matches for pemetrexed or enfortumab are not new pembrolizumab approvals.
CT permissions and SEC minutes [5–7]	Several manufacturers have development activity.	Clinical-trial permission or an SEC recommendation is not marketing authorisation.

THE THREE POSTURES ARE COHERENT ONLY WITH HONEST LABELS

Originator defence is an immediate commercial posture. Biosimilar challenge is presently a preparation posture, with a gated future commercial branch. Selective access is a hospital or channel strategy within lawful supply, not evidence of a third manufacturer. These positions can coexist without pretending that India already has a conventional multi-brand pembrolizumab market.

Do not publish national market share, Indian molecule revenue, total eligible patients or a number of competing marketed brands from retail listings, trial registries or distributor counts. No audited national estimate is asserted here. Procurement volumes and hospital consumption are separate denominators.

EXACT MOLECULE AND EMERGING PRODUCTS

A TRIAL ROSTER IS NOT A COMPETITOR SHELF

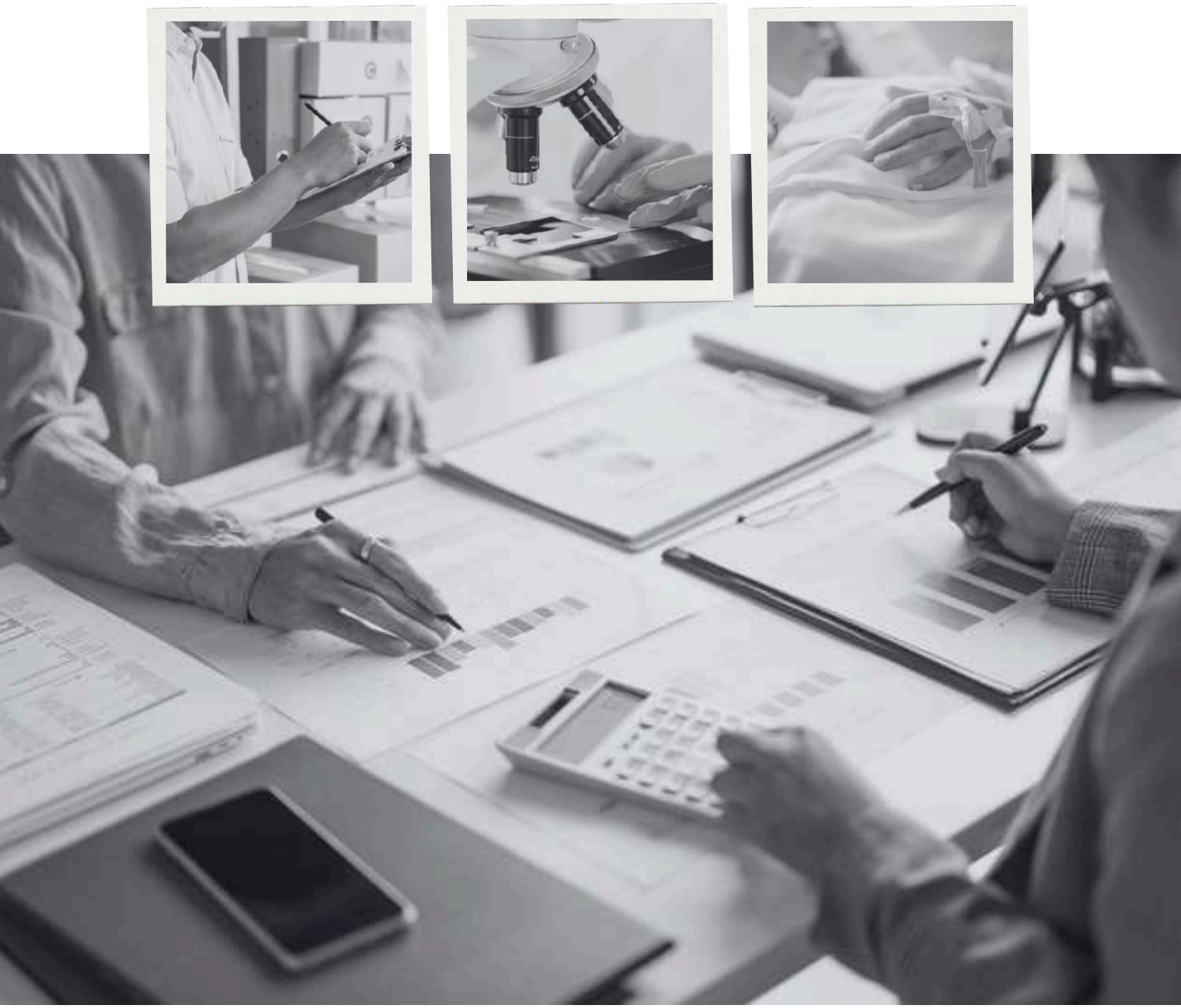
PRODUCT OR ENTITY	VERIFIED PUBLIC STATUS AT CUTOFF	COMMERCIAL USE OF THE EVIDENCE
Keytruda MSD	Originator pembrolizumab; India product presence and regulatory records; 100 mg/4 mL infusion presentation in CDSCO records. [1,2]	Current reference product. Match claims to its Indian label and actual local supply.
Sun Pharmaceutical Industries	September 2026 SEC minutes discuss an amendment to its Phase III pembrolizumab study. [6]	Prospective challenger. No launch, price or market share assumed.
Intas Pharmaceuticals	Pembrolizumab appears in CDSCO clinical-trial permission listings released March 2026. [5]	Development evidence only; no marketed brand asserted.
Hetero Biopharma	May 2026 SEC minutes discuss a comparative Phase III trial amendment. [7]	Development evidence only. Comparator study is not a completed biosimilarity conclusion.
Enzene and Lupin	Each has a pembrolizumab entry in the CT permission table released July 2026. [5]	Potential future entry, subject to completed development, approval and lawful launch.
Kemwell ASP200	CDSCO CT table lists ASP200 pembrolizumab in October 2026. [5]	Investigational candidate, not another retail product.

This is a selected, verified development roster, not an exhaustive pipeline census or a ranking of launch readiness. The table's release date is not necessarily the date of the underlying permission. Research codes, CRO applicants and overseas products must not be counted as independently marketed Indian brands.

WHAT A FUTURE CHALLENGER MUST PROVE

Require the actual CDSCO permission, manufacturing/import licence, exact approved indications and presentation, current Indian PI, comparability evidence, immunogenicity data, quality and cold-chain controls, pharmacovigilance arrangements, lawful market-entry status and reliable supply. Indication extrapolation must follow the permission actually granted. [8,9]

Neither the word "biosimilar" nor a lower price establishes automatic interchangeability. Product switching and documentation remain under the oncology team and hospital pharmacy. No launch date, patent-clearance date, clinical superiority or percentage price discount is forecast here.



ADJACENT CLINICAL AND COMMERCIAL COMPETITION

THE REAL TREATMENT CHOICE IS WIDER THAN THE MOLECULE

A patient's alternative may be another checkpoint inhibitor, a targeted treatment, chemotherapy, local treatment, a clinical trial or supportive care. The relevant set depends on tumour, stage, prior therapy, biomarker and Indian approvals. It is never a universal substitution list.

ADJACENT SET	INDIAN EVIDENCE AND RELEVANCE	BOUNDARY
Nivolumab	Originator Opdyta and Zydus Tishtha are relevant examples. Zydus announced Tishtha's Indian launch on 22 January 2026; CDSCO also records nivolumab manufacture approvals. [3,14]	A nivolumab biosimilar is not a pembrolizumab biosimilar. No cross-molecule interchangeability.
Other PD-1 agents	CDSCO lists Indian approvals for tislelizumab, toripalimab and dostarlimab in specified settings. [2]	Verify each indication, line, regimen and biomarker. Approval is not proof of stock in every hospital.
PD-L1 agents	Atezolizumab and durvalumab have India regulatory records across selected settings. [2,4]	Mechanism-family membership does not make regimens equivalent.
Non-checkpoint treatments	Driver-directed therapy in NSCLC and other tumour-specific regimens can be the clinically correct choice. [15,16]	A strong PD-L1 result must not erase actionable-driver assessment.
Non-drug decisions	Surgery, radiotherapy, symptom control, supportive and palliative care remain part of an appropriate pathway.	No therapy is a service failure merely because it produces no pembrolizumab sale.

COMPARE AT REGIMEN AND EPISODE LEVEL

An adjacent agent's vial price cannot establish the cheaper treatment episode. Compare only clinically appropriate, India-approved alternatives using the oncologist's regimen: dose, schedule, co-treatment, treatment horizon, administration, monitoring, toxicity care, patient travel and verified payer support. Avoid cross-trial efficacy rankings and survival comparisons unsupported by suitable head-to-head evidence.

Tishtha's company-announced January launch prices were INR 28,950 for 100 mg and INR 13,950 for 40 mg. Those are dated nivolumab launch-price signals, not current procurement quotes, pembrolizumab-equivalent doses or proof of savings for a particular patient. [14]

The competitive threat is treatment-level affordability and hospital execution, not just another logo on the same molecule. No complete adjacent-brand inventory or relative market-share ranking is claimed.





PRICING PROCUREMENT AND ACCESS



A LOWER HEADLINE PRICE IS NOT A FUNDED TREATMENT PLAN

Verified price anchor: NPPA's list based on company submissions through 2 November 2026 shows Keytruda, pembrolizumab 100 mg injection, pack size 1, at INR 2,16,500 for both old and revised MRP (entry 824, PDF page 59). It is a listed MRP, not a net hospital acquisition price or a patient's final bill. [10]

The October trade-margin intervention covers pembrolizumab and is scheduled to take effect on 9 November 2026. As of this document's 3 November cutoff, that date is still ahead. Do not apply the government's "up to" reduction headline to Keytruda: its listed entry is unchanged. Recheck the effective price list and invoice at supply. [10,11]

ACCESS ROUTE	VERIFY BEFORE INITIATION	WHAT THE SERVICE MAY DO
Private insurance or employer payer	Policy, indication and hospital eligibility; pre-authorisation; limits, copay, exclusions and renewal requirements.	Track documents and written decisions; never promise coverage.
Public procurement or scheme	Tender specifications, sanctioned budget, formulary, authorised supplier and applicable package approval.	Track a valid procurement or reimbursement process; no bid manipulation.
Manufacturer assistance	Current written programme rules, eligibility, cycle structure, renewal, supply route and exit arrangements.	Help submit patient-authorised documents through hospital access staff.
Self-pay or charitable funding	Full episode estimate, recurring affordability, travel and supportive-care costs, and contingencies.	Explain approved options and route funding questions; no steering to loans or unverified sellers.



AIIMS New Delhi publishes a proprietary procurement notice for pembrolizumab 100 mg. This demonstrates an institutional purchasing route; it does not prove a national contract, current award price, multiple manufacturers or universal public reimbursement. Multiple bids may be authorised resellers of the same originator. [12]

The 2025 customs notification names MSD's Key-PAP 1.0 and KIRAN for pembrolizumab. It does not establish today's patient eligibility, guaranteed free cycles or actual enrolment. PM-JAY oncology guidance calls for stage/package pre-authorisation; scheme membership alone is not evidence that pembrolizumab is funded. [13,29]

A financing worksheet should itemise drug, co-treatment, testing, chair/day-care, monitoring, travel and contingencies. Use the prescribed regimen and actual quotes; no annual drug-cost estimate is fabricated from vial MRP.

SEGMENT THE CARE PATHWAY

ONE MOLECULE CONTAINS SEVERAL DIFFERENT HOSPITAL JOURNEYS

Choose the entry segment by a clinical task and an operating setting, then test its commercial relevance. Do not estimate the addressable population from total cancer incidence or treat every immunotherapy discussion as a pembrolizumab opportunity.

PATHWAY SEGMENT	WHERE THE WORK DIFFERS	SUITABLE FIRST TASK
Metastatic NSCLC	Histology, driver assessment, PD-L1, prior treatment and fitness shape options. Symptom burden can make delay urgent.	Track clinician-ordered reports to documented interpretation; never wait for a service checklist in an emergency.
Early or perioperative disease	Surgical, medical and radiation teams share timing; curative intent changes the harm of avoidable delay.	Coordinate a dated MDT plan and phase-transition review.
Advanced breast GI or gynaecological cancer	CPS, HER2, MSI/MMR, disease site and treatment line have different roles.	Use one tumour-specific report and regimen checklist.
Biomarker-defined pathways	A marker is relevant only with the tumour, stage, assay and approved treatment context.	Resolve specimen and report issues; oncology interprets eligibility.
Existing treated patient	Toxicity, interruptions, response assessment and outside emergency visits can fragment care.	A reliable symptom-to-oncology and hospital re-entry handover.

Hospital context determines feasibility : A tertiary centre with in-house pathology can test report-to-decision time. A regional hospital with outsourced testing may first need specimen and result tracking. A public cancer centre may prioritise sanctioned access and scheduling. A private network may need consistent pre-authorisation and cross-site escalation. A stand-alone infusion unit qualifies only with a named prescribing oncology team, emergency capability and an agreed transfer route.

Rank the first pilot opportunity : First - one adult metastatic NSCLC pathway in hospitals with a working pathology interface and 24-hour emergency access. Second: an established immunotherapy cohort needing symptom and re-entry coordination. Third: a perioperative pathway after multidisciplinary scheduling is proven. These are implementation recommendations, not claims that NSCLC is the largest or most profitable Indian pembrolizumab segment.

Clinical context: Indian lung guidance [15], ASCO [16] and tumour-specific ESMO sources [17,18]. The hospital's current Indian product label remains the deployment gate.

TUMOUR SPECIFIC CLINICAL SPINE

THE TEST MUST ANSWER THE TREATMENT QUESTION

The following is a selection-support map for hospital teams, not a prescribing algorithm or a complete indication list. Approval summaries establish a regulatory anchor; the current Indian PI supplies exact eligibility, dose, duration and warnings. All treatment decisions require the oncologist's documented assessment. [2,4,15–18]

SETTING	REQUIRED DISTINCTION	SERVICE CONTROL
NSCLC advanced	Histology and stage; actionable-driver evaluation; prior therapy and performance status; PD-L1 TPS for the relevant monotherapy question. Combination and monotherapy rules differ.	Record actual assay, TPS and driver results. Do not convert CPS to TPS or apply one threshold to every regimen. Legacy metastatic label wording must be verified before release.
NSCLC resectable or adjuvant	CDSCO records April 2025 perioperative and post-resection indications for selected high-risk adults.	MDT documents resectability, pathological risk, chemotherapy sequence and surgery plan. "Lung cancer" alone is insufficient.
TNBC metastatic versus early	May 2023 record: advanced combination pathway uses CPS at least 10 and a specified prior-treatment condition; early high-risk pathway has a different neoadjuvant/adjuvant structure.	Do not impose the metastatic CPS requirement on the early pathway. Confirm ER, PR and HER2 classification and current Indian PI.
Cervical cancer	Persistent/recurrent/metastatic combination and previously untreated FIGO 2014 III–IVA chemoradiation pathways are separate approvals.	The advanced pathway has a PD-L1 condition; the locally advanced pathway is not a substitute for radiotherapy and brachytherapy planning.
Gastric GEJ and oesophageal	Histology, HER2, CPS and tumour site matter. November 2025 record includes HER2-negative gastric/GEJ combination with CPS at least 1.	Do not transfer that threshold to oesophageal disease. Resolve exact indication wording and partner regimen before activation.

PD-L1 = programmed death ligand 1; TPS = tumour proportion score; CPS = combined positive score; TNBC = triple-negative breast cancer; GEJ = gastro-oesophageal junction. These scores are not interchangeable. Approval dates here follow the published CT-18 list, not SUGAM administrative closure dates.

TUMOUR SPECIFIC CLINICAL SPINE

BIOMARKER POSITIVITY DOES NOT CREATE UNIVERSAL ELIGIBILITY

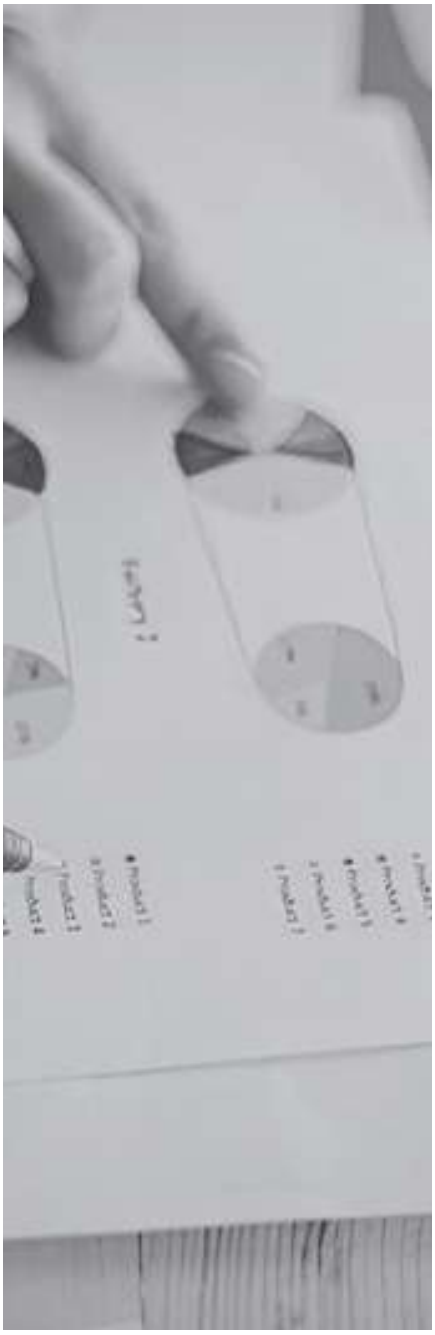
SETTING	REGULATORY OR CLINICAL ANCHOR	PATHWAY RULE
MSI-H or dMMR colorectal cancer	CDSCO March 2024 record includes first-line metastatic adult CRC monotherapy. [2]	Use a validated MSI/MMR result and tumour-specific interpretation. Discordant or indeterminate findings return to pathology and oncology.
Renal cell carcinoma	May 2023 record includes selected first-line advanced combination and adjuvant settings. [2]	Confirm risk, stage, partner therapy and monitoring. Do not invent a universal PD-L1 gate.
Head and neck cancer	August 2026 record adds a perioperative pathway for selected resectable locally advanced adult HNSCC with CPS at least 1. [2,4]	Separate this from recurrent/metastatic regimens. Plan surgery, radiation and systemic-treatment handovers.
Biliary tract cancer	November 2025 record includes a first-line gemcitabine/cisplatin combination in a defined advanced adult setting. [2]	Do not add a mandatory PD-L1 gate absent from the actual approved indication. Preserve co-treatment safety checks.
Melanoma and classical Hodgkin lymphoma	March 2024 record adds selected adjuvant melanoma and relapsed/refractory adult cHL settings. [2]	Confirm prior therapies, surgical status or transplant history. Do not broaden to all stages or paediatric patients.
Urothelial and other settings	A 2026 enfortumab-combination record exists, but public summaries differ in scope. Other international uses cannot be presumed Indian approvals. [2,4,19]	Reconcile both partner labels and the actual permission. Keep unresolved pathways inactive in sponsor deployment.

THE LIMITS OF TISSUE AGNOSTIC CLAIMS

MSI-H/dMMR and tumour mutational burden are distinct biomarkers. A US tissue-agnostic indication is not an Indian authorisation. The FDA changed its TMB-high threshold to at least 13 mutations/Mb on 16 October 2026; that is a US change, not an instruction to apply either 10 or 13 in India. No general Indian TMB-based pathway is authorised by this note. [20]

Endometrial, additional urothelial and other overseas indications require a verified Indian approval-specific addendum before commercial deployment. A clinically appropriate off-label decision, if made under hospital governance, remains separate from sponsor promotion and from this programme's eligibility rules.





CLINICAL RELEASE GATE

EVIDENCE SUPPORT CANNOT REPLACE A CURRENT INDIAN LABEL

Before any live pathway, the hospital medical lead and product medical/regulatory owner must reconcile the current Indian PI, actual approval letter, tumour guidance and local protocol. Record version, date, tumour, stage, line, biomarker, regimen partners, intended duration and responsible oncologist. A foreign label is useful for safety surveillance; it is not permission to promote an Indian indication.

Three public record discrepancies to resolve : The CT-18 list and SUGAM use different dates for some administrative records. SUGAM groups HER2-positive gastric wording with an April 2025 result that is not reproduced in the corresponding published CT-18 entry. The 2026 enfortumab record also has narrower wording in the published list than in the search summary. Use the signed permission and Indian PI to resolve these differences; do not choose the broadest version. [2,4]

A real India affordability nuance : The February 2026 DHR/DGHS lung guideline conditionally supports consideration of lower-dose pembrolizumab in selected advanced NSCLC patients when standard treatment is unaffordable or unavailable, with very low-certainty evidence and documented rationale and informed consent about uncertainty. This does not amend the marketing label or establish dose equivalence. It is not a service-generated or field-promoted cost-saving regimen. [15]

CLINICAL CHECK	ACCOUNTABLE TEAM
Baseline risk and co-treatment	Oncologist reviews autoimmune disease, organ transplant, prior immune toxicity, infection risk, organ function, medicines and relevant reproductive counselling.
Monitoring plan	Hospital sets baseline and interval tests, symptoms, imaging and clinical review for the exact tumour and regimen.
Immune toxicity and emergencies	Oncology and emergency teams distinguish toxicity, infection, progression and co-treatment effects; they determine grading and urgent management.
Hold rechallenge or stop	Only authorised clinicians decide treatment interruption, immunosuppression, rechallenge, discontinuation or transition.

The service never selects a dose or regimen, reassures away a new symptom, calculates eligibility from a questionnaire, or tells a patient to self-treat. No automated “safe to infuse” decision is permitted.

Safety basis: international pembrolizumab PI and ASCO/SITC toxicity guidance [19,21,22]. The pilot is adult-only; paediatric or especially complex pathways require separately approved specialist governance.

THE CENTRAL PATHWAY DRIFT



THE DANGEROUS GAP IS AN UNRESOLVED HANDOVER

The central hypothesis is that clinically consequential delay accumulates between teams: pathology sends a report, a payer asks for clarification, an infusion date is offered, or a patient mentions diarrhoea to a receptionist. Each action can be recorded as complete while the decision remains unfinished. The pilot must establish which gaps actually occur at each hospital; this note does not invent Indian prevalence.

MOMENT THAT MATTERS	PATIENT RISK AND CARE TEAM TASK	CREDIBLE COMMERCIAL VALUE
1 Indication and line	Wrong pathway. Oncologist records diagnosis, stage, prior therapy and label-specific rationale.	Trust in disciplined implementation, not expanded eligibility.
2 Tissue and tests	Inadequate specimen or wrong assay. Pathology confirms ordered tests, adequacy and due dates.	Fewer avoidable report-chasing tasks.
3 Report and MDT review	Result arrives without interpretation. Oncology/MDT records the treatment or further-workup decision.	A useful institutional relationship.
4 Financial decision	Initiation without sustainable access. Access team documents costs, coverage and unresolved gaps.	Transparent and dependable access execution.
5 Infusion readiness	Slot exists but authorisation, supply or clinical clearance is missing. Pharmacy, nurse and prescriber close readiness checks.	Fewer avoidable administrative cancellations.
6 New symptoms	Possible serious toxicity is dismissed. Hospital nurse routes urgent clinical assessment and records acknowledgement.	Credibility from reliable escalation; no retention target.
7 Interrupted care or ED visit	External treatment is unknown. Oncology reconciles the episode and issues the next plan.	Better continuity across hospital boundaries.
8 Response and toxicity review	Treatment proceeds without the due review. Oncology interprets assessment and documents disposition.	Appropriate care-process completion.
9 Transition or discontinuation	Patient exits without safety follow-up. Team gives a named receiving service and delayed-toxicity instructions.	Trust that survives a clinically appropriate stop.

All commercial values are hypotheses. Correct non-initiation, treatment hold, another therapy, transfer and palliative-care referral are valid outcomes. The service must not label these decisions as lost conversions.

ONE HOSPITAL SUPPORT ENGINE

BIOMARKER TO TREATMENT TO TOXICITY REVIEW

Use one hospital identity, one accountable clinical team and one due-action worklist. The engine joins patient education, factual navigation, clinical handover and independent professional education. Its modules adapt to the tumour; its operating rules remain consistent.

MODULE	ENTRY AND OUTPUT	OWNER
A Biomarker and decision readiness	An oncologist orders workup. Output: reports reconciled and a documented clinical decision, including no immunotherapy.	Pathology lead and treating oncologist.
B Access and infusion readiness	Treatment is independently selected. Output: written access status, authorised supply, appointment and clinician clearance.	Access officer, pharmacy and infusion team.
C Symptoms and immune toxicity review	Patient starts treatment or joins with a documented regimen. Output: reported concerns reach the hospital clinician and receive a recorded disposition.	Oncology nurse and duty oncology team.
D Review re-entry and transition	Assessment, interruption, external care or discontinuation is due. Output: reconciled episode and a named next step.	Treating oncologist with receiving team.

Two entry doors prevent a promotional funnel : Before treatment selection, the hospital may use a general, brand-neutral diagnostic navigation module for the relevant tumour cohort regardless of eventual therapy. After selection, regimen-specific support begins only when the clinical plan and consent are recorded. The funded service cannot require a pembrolizumab prescription as the price of test navigation, education or urgent support.

The minimum viable system : Use the existing hospital record, a restricted task list and approved phone or message channels. Each task contains an owner, original due time, source record, current status, reason for delay and clinician disposition where needed. A QR link may open hospital information; it does not enrol a patient or create consent by itself. Paper and telephone routes must remain available.

The narrow first release includes report-to-decision tracking, first-infusion readiness and symptom-to-hospital review. Add longitudinal response and transition modules only after these handovers work. No sponsor dashboard contains identifiable patients or a list of sales opportunities.

This is a proposed operating model. Inditech's potential role is strategy, content design, Academy coordination and implementation support under hospital control. It confers no clinical authority, exclusive mandate or claim of existing deployment.

MODULE A

CLOSE THE REPORT TO DECISION LOOP

Entry and minimum record : The oncologist specifies the clinical question and orders only appropriate tests. Record tumour and histology, stage, specimen identifier, collection date, requested assay, performing laboratory, expected turnaround and named reviewer. Capture a baseline due date agreed by the hospital rather than advertising an unverified national turnaround standard.

STEP	TASK AND RESPONSIBILITY	CLOSURE EVIDENCE
Specimen readiness	Pathology checks identity, tissue adequacy and assay suitability. Navigator tracks dispatch and receipt without interpreting slides.	Accepted sample or documented re-biopsy/alternative plan by the clinical team.
Result readiness	Pathology records method, score or result, limitations and authorisation. Track missing components and external reports.	Final authorised report linked to the correct patient and order.
Clinical interpretation	Oncologist checks assay context, tumour/line and other treatment-relevant biomarkers. Refer difficult or discordant cases to MDT.	Signed interpretation and decision; raw positivity is not completion.
MDT handover	Coordinator schedules the appropriate board; clinicians review clinical options and patient goals.	Dated MDT recommendation, responsible clinician and next action.
Unresolved result	Escalate on the original due date to pathology and oncology; clinical urgency overrides routine queues.	Revised plan with reason, urgency and an accountable owner.

What the module must not do : No mandatory blanket PD-L1/MSI/TMB panel across cancers. No repeat biopsy to improve a sponsor conversion rate. No report-reading bot that labels a patient “eligible for pembrolizumab”. No free test tied to drug purchase or automatic sharing of pathology results with a field team. The hospital assesses any test funding for lawful purpose, need and undue influence.

Practical check in : Proposed cadence: verify receipt within one working day of dispatch confirmation; inspect the pending-results list each working day; flag a missed agreed turnaround the same day; record clinician review within the hospital’s risk-based timetable. These are pilot settings, not permission to delay care. An urgent patient bypasses the service queue.

Clinical basis: *Indian lung guidance and current professional guidance [15–18]. The process works even when results lead to targeted treatment, another regimen, further workup or supportive care.*

MODULE B

RESOLVE ACCESS BEFORE CONFIRMING TREATMENT READINESS

A support worker may organise an appointment; only the oncology team may authorise treatment. Keep financial readiness, stock readiness and clinical readiness as separate fields. A tick in one field must never populate the others.

READINESS DOMAIN	REQUIRED HOSPITAL TASK	IF NOT READY
Treatment and consent	Prescriber confirms exact regimen and current order. Clinical team explains benefits, risks, alternatives and treatment consent.	Return to oncology; no service recommendation or substitute order.
Financial access	Access officer confirms written payer/PAP decision, patient share, coverage period, unresolved costs and renewal dates.	Escalate to the access lead and oncologist; discuss lawful alternatives through clinicians.
Product and supply	Pharmacy verifies authorised source, actual product, batch, expiry, cold-chain record and availability for the planned order.	Quarantine suspect supply; follow pharmacy/PV procedures. No informal purchase instructions.
Clinical readiness	Nurse and prescriber review symptoms, required tests and co-treatment issues under the hospital protocol.	Obtain clinical review; a navigator cannot clear or cancel the regimen independently.
Visit readiness	Infusion centre confirms chair, trained staff, emergency capability, patient travel and contact plan.	Rebook with the clinical team and document reason; preserve the original intended date.

A practical pre visit sequence : Proposed setting: check administrative readiness two working days before the planned visit; contact the patient or authorised caregiver the day before to confirm logistics and ask about new concerns; perform clinical clearance on the treatment day under hospital practice. A new symptom goes straight to the clinical route, even if all funding and appointment checks are complete.

After a missed appointment, the hospital contacts the patient on the same working day and distinguishes illness, admission, finance, transport, choice and administrative failure. It does not send a “complete your next dose” message until the oncology team has confirmed the next action.

Support without inducement : Navigation is offered on neutral clinical and need criteria. Any manufacturer assistance is a separately governed programme with its own lawful terms. Do not make hospital service funding, nursing support, education or test access conditional on prescribing volume, formulary preference or exclusive supply. [23,24]

MODULE C

A SYMPTOM REPORT MUST REACH A PERSON WHO CAN ACT

Immune-related adverse events can be serious or fatal, involve multiple organs and appear after treatment has stopped. A patient's new symptom may also reflect infection, progression or co-treatment toxicity. Only the clinical team makes that distinction. [19,21,22,30]

PATIENT REPORT	SERVICE RESPONSE	CLINICAL RESPONSIBILITY
Severe breathlessness, chest pain, collapse, confusion, seizure, rapidly worsening weakness or difficulty swallowing	Direct immediate emergency assessment using the hospital-approved route. Do not ask the patient to wait for a message or complete a questionnaire. Notify the duty team in parallel.	Emergency team stabilises and contacts oncology; specialists assess the cause.
Severe abdominal pain, bloody diarrhoea, inability to keep fluids down, major bleeding, extensive blistering or skin peeling	Use the urgent/emergency route immediately according to hospital protocol; record time and attempted handover.	Hospital team assesses severity, dehydration, infection and possible immune toxicity.
New or worsening diarrhoea, cough, rash, jaundice, unusual fatigue, headache, dizziness, thirst, frequent urination or reduced urine	Prompt same-day contact with the oncology clinical route; escalate worsening or severe features immediately. Do not give routine reassurance.	Oncology nurse/clinician assesses urgency, orders evaluation and documents instructions.
Reaction during infusion	Alert the infusion nurse immediately. The navigator does not manage the infusion.	Trained clinical staff manage the infusion and emergency response under protocol.

These examples are not exhaustive and are not a patient self-triage score. The hospital supplies the actual 24-hour emergency contact and backup route before release. Every patient is told that scheduled check-ins and digital messages are not continuously monitored and must never delay urgent care.

Escalation is closed only after acknowledgement : The receiving clinical team records acknowledgement, assessment route and disposition. An unanswered message remains open. Proposed operating rule: urgent staff handovers are live calls, with immediate escalation to the duty clinician or emergency service if the first route fails. A non-clinical team never waits for the next scheduled round to clear an urgent queue.

No patient instruction to start steroids, antidiarrhoeals or other treatment is supplied by this service. Holds, immunosuppression, tapering, rechallenge and discontinuation are clinician decisions. Detailed medical management remains in the hospital's approved toxicity protocol.

MODULE D

KEEP THE ONCOLOGY TEAM CONNECTED AFTER INTERRUPTION OR EXIT

Response and toxicity review : At treatment initiation, the oncologist records the planned clinical review, required monitoring and first response-assessment window. The coordinator tracks those dates and the completion of ordered investigations. Oncology interprets response and toxicity together, including whether apparent progression needs further assessment. The service does not label scans, infer pseudoprogression or authorise continued therapy.

Hospital re entry after external care : Ask about emergency visits, admissions and new prescriptions at each contact. With consent, obtain the external discharge record, symptom onset, investigations and treatments, then arrange oncology review. The receiving clinician reconciles medicines and determines the next treatment step. A discharge summary received is not a completed oncology handover.

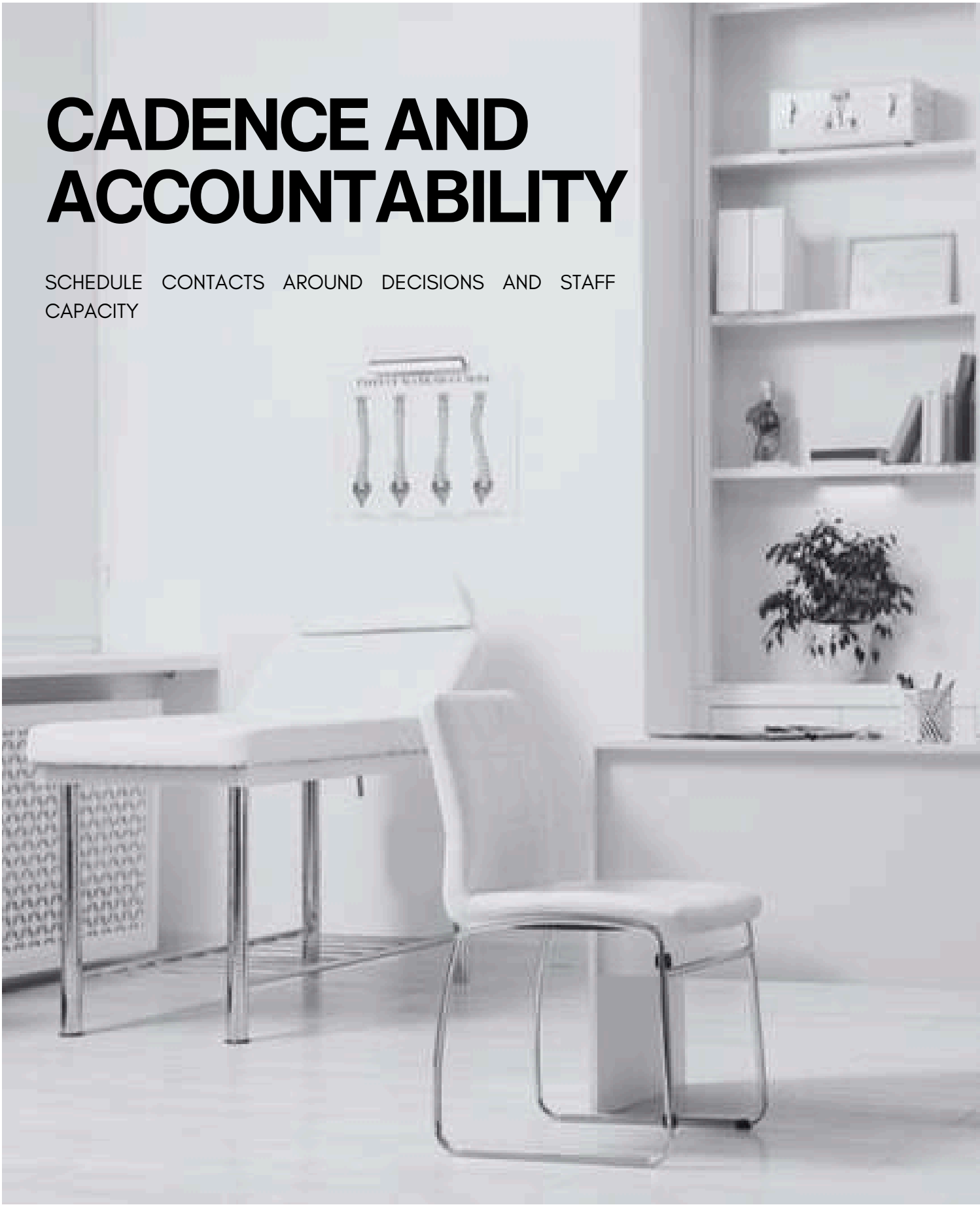
EVENT	NEXT ACTION	REQUIRED CLOSURE
Clinician-directed treatment hold	Suspend routine infusion nudges; retain symptom and appointment support under the current care plan.	Named reviewer, investigation/monitoring plan and next review date.
Rechallenge under consideration	Route to treating oncologist and relevant specialists; no product-team approval role.	Recorded benefit-risk decision and revised monitoring plan.
Progression or change of therapy	Support the new clinic plan and receiving service; reconcile obsolete messages.	New plan acknowledged, old regimen reminders retired.
Discontinuation or transfer	Provide hospital instructions for delayed toxicity and who to contact; transfer records lawfully.	Receiving team and patient know the next step and responsibility.
Palliative or end-of-life care	Offer practical support consistent with patient goals and the clinical plan.	Appropriate palliative-care contact; no commercial win-back activity.

Follow up has an owner beyond day ninety : Proposed operational minimum: a hospital check within seven days after a significant interruption, discharge or transition, sooner when clinically required. At stopping, the oncologist specifies follow-up duration and contact dates for delayed events; there is no universal service expiry that declares toxicity risk over. Patients are not stranded when a pilot or sponsor contribution ends.

Clinical basis: delayed toxicity and multidisciplinary care principles [19,21,22,30]. The suggested contact interval is an operating assumption, not a toxicity-treatment standard.

CADENCE AND ACCOUNTABILITY

SCHEDULE CONTACTS AROUND DECISIONS AND STAFF CAPACITY



TRIGGER	PROPOSED CONTACT OR REVIEW	ACCOUNTABLE OWNER
Hospital referral and consent	Confirm identity, contact preference, language, care owner and current clinical plan before first service contact.	Hospital coordinator; clinical lead approves entry.
Tests outstanding	Working-day worklist review; escalation on a missed locally agreed due date.	Pathology liaison and oncologist.
First infusion due	Administrative checks at minus two working days; patient logistics check the day before; clinical clearance on the day.	Access officer, pharmacy, infusion nurse and prescriber.
After first infusion	A hospital-directed check at 48–72 hours, followed by weekly contacts during the first six weeks if locally appropriate.	Oncology nurse; navigator records factual responses only.
Later cycles	Pre-visit check and review of any new symptoms; intensity adjusted by oncology to regimen and risk.	Oncology nurse and treating team.
Any urgent symptom	Immediate emergency routing or live clinical escalation; never wait for the routine contact.	Duty clinical team and emergency department.
Hold admission transfer or stop	Risk-based early review; proposed operational check within seven days, plus the clinician's ongoing plan.	Treating and receiving oncology teams.
Process oversight	Weekly overdue-task and workload review; monthly medical, PV and governance review.	Hospital programme lead and independent oversight.

The cadence is a pilot hypothesis. More messages are not necessarily safer. The hospital may intensify, reduce or stop routine contacts while preserving access to care. No reply means status unknown, not well. Agree contact attempts and caregiver permissions in advance; unresolved safety concerns go to the clinical team.

SEPARATE THE ROLES

Oncologist: clinical decisions and disposition. Nurse: approved assessment and escalation within professional scope. Coordinator: logistics and factual capture. Pathologist: report validity and interpretation within the laboratory. Pharmacist: product verification and dispensing. Access officer: funding documentation. Academy: independent scientific review and education. Sponsor: lawful funding, product information and required safety obligations; no patient selection. Field team: institutional introduction and approved HCP discussion; no case access.

Operating hours, backup staff and after-hours instructions must be written into the local version. A shared dashboard without an identified response owner is not an escalation service.

PATIENT EDUCATION

TEACH THE NEXT ACTION WITHOUT CREATING DRUG DEMAND

Patient materials carry the hospital or clinic identity. They use plain language, local-language audio where useful, and teach-back. They do not display product promotion, imply that immunotherapy is the best option, solicit demand for pembrolizumab or promise a treatment response. Sponsorship disclosure, where required, is factual and separated from promotional branding.

Example hospital invitation : “Your hospital offers support with reports, appointments and questions about your care. Your oncology team decides which treatment is suitable. Joining is optional and does not change your access to care. We will explain which information we use and who can see it. You can ask us to stop routine support at any time.”

Example check in after treatment : “Since your last contact, have you developed any new or worsening problem, including changes in breathing, bowel movements, skin, energy, thirst, urination or strength? Please tell your oncology team promptly. Do not wait for this check-in if you feel unwell. The team will decide what assessment you need.”

Example urgent care message : “For severe breathing difficulty, chest pain, collapse, confusion, severe weakness or another rapidly worsening problem, seek emergency care immediately using your hospital’s emergency route. Do not wait for a message reply. Tell the emergency team about your cancer treatment, even if it has stopped, and show your treatment alert card.”

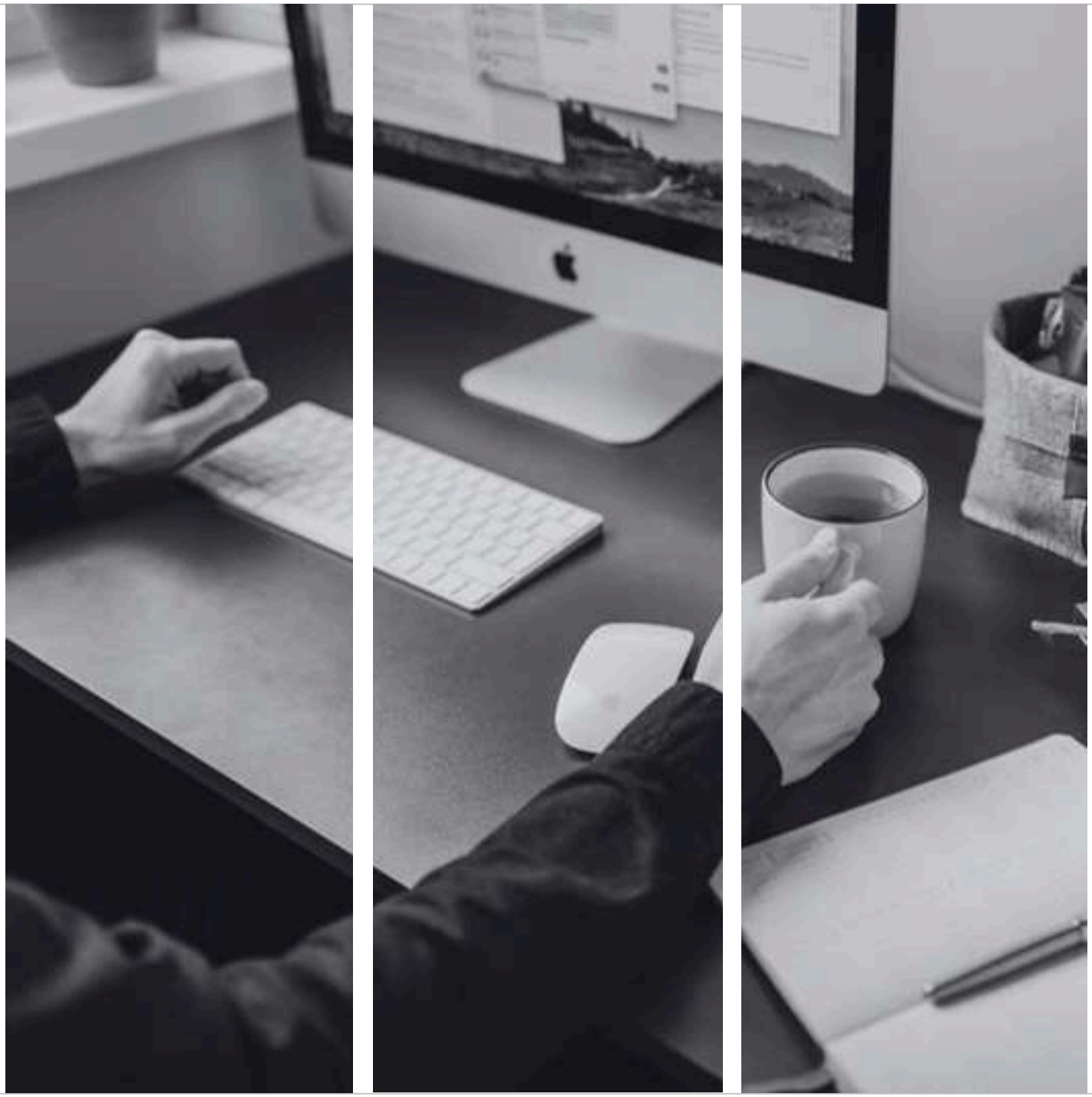
Example appointment and review message : “Your hospital review is due on the date in your care plan. Bring the reports and medicine list requested by your team, and tell them about any emergency visit or new symptom. This reminder does not confirm that treatment is safe to receive. The clinical team will review you.”

PATIENT ASSET	MINIMUM CONTENT	PATIENT ASSET
Treatment alert card	Hospital contacts and backup route; treatment name and dates entered by clinicians; current concerns; instruction to show the card during emergency care. No promotional claims.	**Treatment alert card**
One page care plan	What is due next, who reviews it, appointment details, contact hours and consent preferences.	**One page care plan**
Short symptom guide	Illustrative red flags, prompt reporting, delayed events and no self-treatment instructions.	**Short symptom guide**
Access information sheet	Verified documents needed, case officer, decision status and clear statement that support does not guarantee coverage.	**Access information sheet**

CLINICIAN AND HOSPITAL ASSETS

BUILD A SMALL SET OF RECORDS THAT CLOSE THE LOOP

ASSET	CONTENT AND OWNER	RELEASE CHECK
Tumour pathway sheet	Oncology-approved indication, stage, line, biomarkers, co-treatment and review checkpoints.	Indian PI and guidance reconciled; exact version recorded.
Pathology readiness form	Order, specimen, assay, expected date, result and reviewer; pathology lead.	Patient/specimen matching and incomplete-result scenario tested.
Access and visit checklist	Funding status, supply, logistics and separate clinical clearance; hospital operations.	No field infers treatment approval from appointment or payment.
Symptom and handover record	Patient's words, time, onset, location, attempted contact, receiving clinician and disposition; nursing lead.	Emergency drill and unresolved-handover test passed.
Oncology review brief	Current plan, due assessments, reported concerns, outside care and open questions; coordinator assembles, clinician interprets.	Source traceability; no automated clinical conclusion.
Product evidence dossier	Permission, current Indian PI, quality, PV, supply and substantiated claims; product medical/regulatory team.	HCP-only access and claims review; separate from patient support.
Education package	Six mini-CMEs, lectures, cases, assessments and practical tools; independent academic body.	Written scientific approval and explicit certificate scope.
Operational dashboard	Overdue tasks, closure, workload and safety routing; hospital programme lead.	Role-based access; sponsor sees only approved anonymised aggregation.



A USEFUL REVIEW BRIEF

Illustrative fictional record: “Metastatic NSCLC workup: external pathology received; molecular report still pending. Patient reports new breathlessness today. Coordinator contacted the hospital nurse at 10:05; nurse directed immediate assessment and notified duty oncology. First-infusion appointment remains provisional. Access authorisation expires next week. Oncology decision and next date awaited.”

This brief gives facts and ownership. It does not infer pneumonitis before treatment, call the patient eligible, or treat the planned infusion as compulsory. Every summary must link back to the source record and allow correction by the clinical team.

INDEPENDENT ACADEMY GOVERNANCE

AN ENDORSEMENT IS A REVIEW OBLIGATION NOT A LOGO

An independent oncology academic body may be invited to review the patient-service standard and education programme. Approval is prospective. No Academy, society, institution or faculty member is represented as having endorsed this playbook, a medicine or a sponsor.

OBJECT OF REVIEW	INDEPENDENT RESPONSIBILITY	EVIDENCE TO RETAIN
Clinical service standard	Approve adult scope, tumour modules, escalation boundaries, patient language and clinical ownership.	Signed version approval, reviewer identities, conflicts and expiry.
Six educational modules	Select faculty, assess evidence balance, include alternatives and review cases and assessments.	Approved PDFs, lecture scripts/videos, references and assessment keys.
Nurse and coordinator readiness	Define training and observed handover competence within professional scope.	Completion record, scenario performance and remediation.
Learner certificate	Certify only completion or assessed learning actually delivered.	Exact certificate wording, attendance and assessment evidence.
Ongoing review	Withdraw outdated or unsafe assets; control updates and corrections.	Version register, change log and withdrawal notices.

Independence must survive an unwelcome conclusion : The academic body must be free to narrow the programme, reject an asset, recommend a non-immunotherapy pathway or publish an unfavourable process finding. Sponsorship is disclosed. Faculty remuneration, if permitted, reflects legitimate work and fair value under applicable rules, never prescriptions or procurement influence. Commercial teams do not select favourable cases or edit scientific conclusions. [23,24,28]

“Academy reviewed” describes a defined content version. It does not mean regulatory approval, accredited CME credit, hospital accreditation, superior drug efficacy or a prescriber qualification. Recognised educational credit requires the relevant authority’s separate approval. No certificate is linked to patient enrolment or product use.

Practical approval workflow : Hospital medical lead defines scope; independent faculty review sources and assets; nursing and emergency leads test the escalation route; legal, privacy and PV leads review implementation; the academic body records its decision. New clinical content remains inactive until its review is complete. An independent review fee or grant must not disguise payment for access to a prescriber.

SIX MONTH EDUCATION PROGRAMME

MONTHS ONE TO THREE ESTABLISH FIT READINESS AND URGENT RECOGNITION

Each month contains a concise mini-CME PDF, a 12–15 minute expert video lecture, a short nurse learning segment, one practical tool, a fictional or lawfully de-identified case and five assessment questions. These are curriculum specifications within this playbook, not a claim that six videos or accredited courses already exist.

MONTH AND CASE	MINI CME AND EXPERT LECTURE	PRACTICE OUTPUT
1 A positive PD-L1 report before the molecular result	Topic: tumour, stage, line and assay before treatment choice. Faculty: medical oncologist and molecular pathologist. Distinguish TPS/CPS, driver results, missing tissue and India label versus international guidance. [2,15,16]	Tumour-specific readiness sheet. Assessment tests whether the learner pauses an unsupported eligibility conclusion. Nurse focus: specimen/report identity and routing.
2 A funded first cycle with an unresolved next cycle	Topic: access, procurement integrity and safe infusion readiness. Faculty: oncologist, oncology pharmacist and hospital access lead. Explain payer/PAP conditions, authentic supply, co-treatment and clinical clearance. [10–13,23]	Access and readiness checklist. Assessment separates funding, stock, appointment and clinical authorisation. Nurse focus: pre-visit concerns and handover.
3 Diarrhoea and fatigue reported between visits	Topic: recognising possible immune toxicity without diagnosing it from a message. Faculty: oncology and emergency clinician with oncology nurse. Include infection and co-treatment differentials and urgent red flags. [19,21,22,30]	Escalation map and live handover drill. Assessment requires prompt clinical routing, not self-treatment advice. Nurse focus: acknowledgement and disposition.

EDUCATION MUST CHANGE A VISIBLE TASK

Month one should improve complete report-to-review records. Month two should improve documented access status and reduce avoidable administrative cancellations. Month three should improve successful symptom handovers. These are evaluation hypotheses; attendance or video views alone do not demonstrate safer care.

Proposed learning standard: complete the module, answer at least four of five questions correctly and pass every critical safety scenario after remediation. The Academy must approve the standard. It is neither a regulatory threshold nor permission to practise outside one’s scope.

SIX MONTH EDUCATION PROGRAMME CONTINUED

MONTHS FOUR TO SIX MAKE REVIEW AND SAFE TRANSITION ROUTINE

MONTH AND CASE	MINI CME AND EXPERT LECTURE	PRACTICE OUTPUT
4 A patient attends an outside emergency department	Topic: hospital re-entry, delayed toxicity and medicine reconciliation. Faculty: oncologist, emergency physician and relevant specialist. Review how outside treatment, steroids and ongoing symptoms reach the responsible team. [19,21,22]	Hospital-to-hospital handover brief and alert card. Assessment tests who may authorise restart. Nurse focus: external records and unresolved follow-up.
5 A scan is due while treatment has been interrupted	Topic: response assessment, toxicity monitoring, treatment intent and patient goals. Faculty: tumour-specific oncologist with radiologist. Separate scan completion from clinical interpretation; discuss clinically appropriate holds and changes. [15-18]	Dated review and disposition form. Assessment rejects automatic continuation or an algorithmic progression decision. Nurse focus: tracking the next review.
6 A patient stops treatment while a new product is discussed	Topic: safe transition, evidence appraisal and future biosimilar readiness. Faculty: independent oncologist, pharmacist and academic methods lead. Explain approval, comparability, traceability and the limits of interchangeability claims. [8,9,19,28]	Transition checklist and product-evidence appraisal card. Assessment separates clinical choice from commercial switching. Nurse focus: delayed symptoms and continued contact.

Turn the programme into a learning cycle : A monthly case conference reviews one anonymised process failure, the action taken and whether the same failure recurred. Include correct non-initiation and discontinuation cases. Do not publish patient testimonials, “before and after” response claims or named prescriber success rankings as educational outputs.

The patient curriculum runs alongside it : Patients receive short hospital-approved explanations at the relevant moment: why a specific report is needed; how to prepare for the visit; whom to contact about symptoms; what to bring after an outside admission; and how follow-up continues after stopping. No patient is asked to learn biomarker cutoffs or decide whether a medicine is appropriate.

The 90-day pilot evaluates modules 1–3. Modules 4–6 form the continuation curriculum and require fresh approval where guidance or labels change. Knowledge scores measure learning, not certification of clinical outcomes.

ORIGINATOR LEADERSHIP DEFENCE

DEFEND TRUST BEFORE PRICE BECOMES THE ONLY CONVERSATION

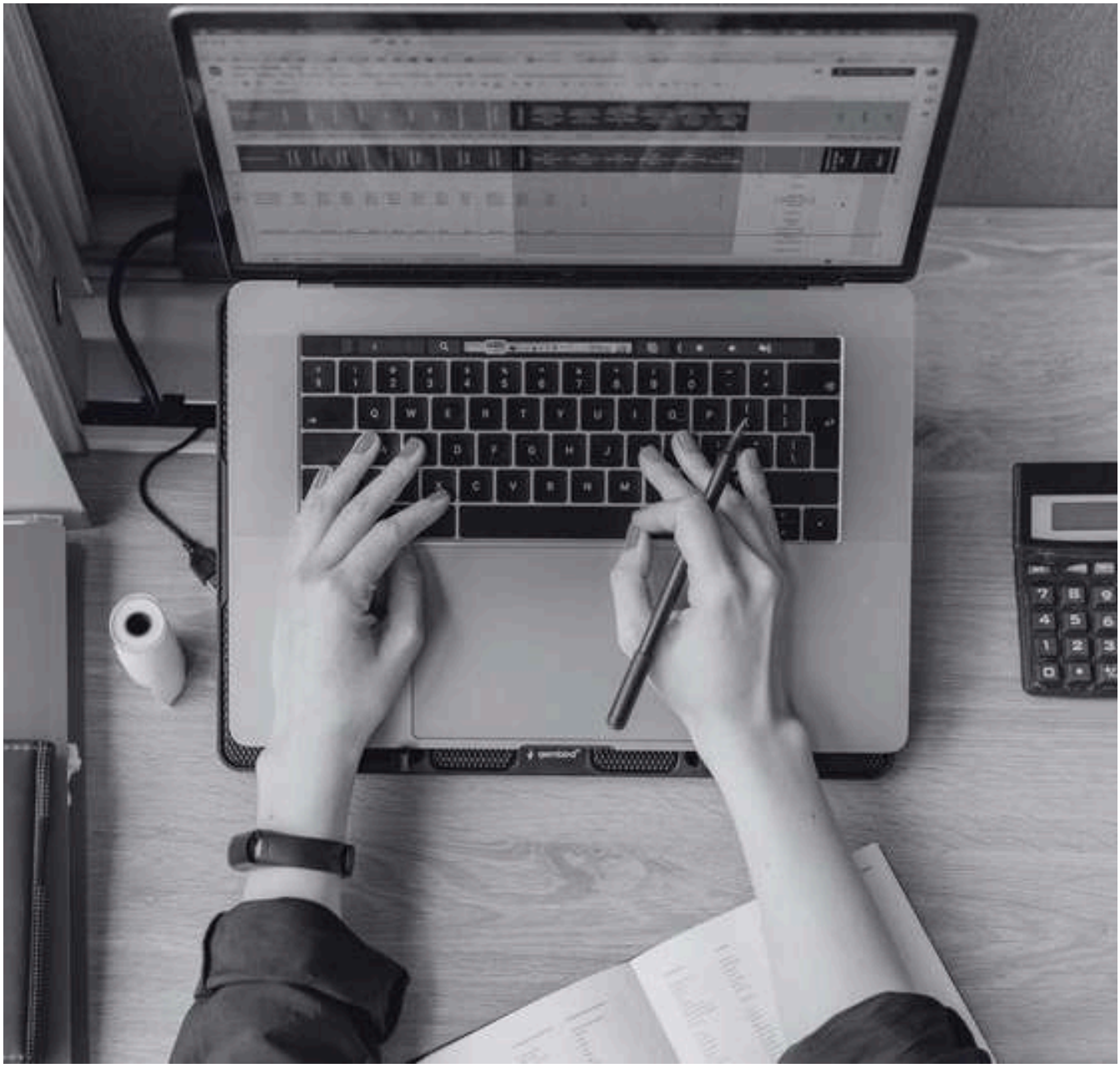


The originator's strongest current position is the verified product, regulatory history and established institutional presence. Its vulnerability is an access or service gap that hospitrals experience directly. A neutral service can strengthen execution, but it cannot justify a premium by implying that an untested competitor is unsafe or that support belongs only to one brand.

THE LEADER STRATEGY

Start in established oncology accounts where report-to-decision, access renewal or symptom handover has a documented gap. Keep the exact product evidence dossier separate from the hospital support standard. Make authentic supply and actual financial terms transparent. Reconcile price changes promptly rather than promising a headline saving the patient never receives.

LEADER MOVE	MECHANISM OF DEFENCE	MEASURE
Strengthen existing accounts	Use account knowledge to identify the highest-burden unresolved task.	Sustained hospital use and completed decisions, not enrolled prescriptions.
Make access dependable	Clarify current assistance terms, renewals and legitimate supply channels.	Time to access decision; unresolved funding episodes and patient-reported burden.
Prepare for a new entrant	Maintain a factual quality, evidence, traceability and supply dossier.	Current dossier and response time to lawful institutional questions.
Preserve service neutrality	Continue support when oncology chooses another therapy or stops treatment.	Neutrality audit and absence of prescription-linked service conditions.



EXPECTED RESPONSE FROM CHALLENGERS

A future approved entrant may compete on net cost, supply and focused hospital service. The leader cannot assume brand familiarity will outweigh a credible institutional value case. Its response should be evidence, transparent access and reliable operations, not fear-based biosimilar messaging or control of hospital data.

Choose this posture when the team has lawful supply, substantial existing institutional relationships and the capacity to repair service gaps. The commercial proxy is sustained qualified institutional consideration and appropriate supply performance. Within-molecule share defence cannot be measured as displacement of currently unverified competitors.

All tactics are recommendations for a market position, not a description of MSD's current programmes or a claim of clinical superiority. A patient's appropriate exit must remain a successful care outcome.

CHALLENGER PREPARATION AND ENTRY

EARN THE RIGHT TO COMPETE BEFORE ASKING FOR SHARE



No marketed Indian pembrolizumab biosimilar was verified at the cutoff. The immediate challenger play is evidence and operating readiness. A pre-launch patient-support scheme must not serve as advance promotion, create demand for an unapproved product, capture a prescriber list or secure future prescriptions. [5–9,23]

STAGE	PERMITTED STRATEGIC WORK	GATE
Now investigational or prospective	Develop quality, comparability and PV capabilities. Conduct lawful research. Support genuinely independent disease education only under appropriate governance.	No product promotion, clinical superiority claim or advance purchasing commitment.
Approval obtained	Reconcile the actual Indian permission, approved indications, label, presentation, traceability, supply and legal market-entry status.	Medical/regulatory and legal release; approval alone is not evidence of launch availability.
Lawful launch	Present a substantiated product dossier and actual institutional price/access terms. Seek formulary consideration through normal processes.	Hospital P&T/procurement review; no free service in return for preference.
Focused adoption	Serve a limited cluster with reliable supply and the same neutral hospital pathway.	No automatic switch; prescriber decision and pharmacy documentation.
Expansion	Broaden only after operating reliability, safety governance and viable economics are demonstrated.	Evidence of reproducibility; no extrapolated national share claim.

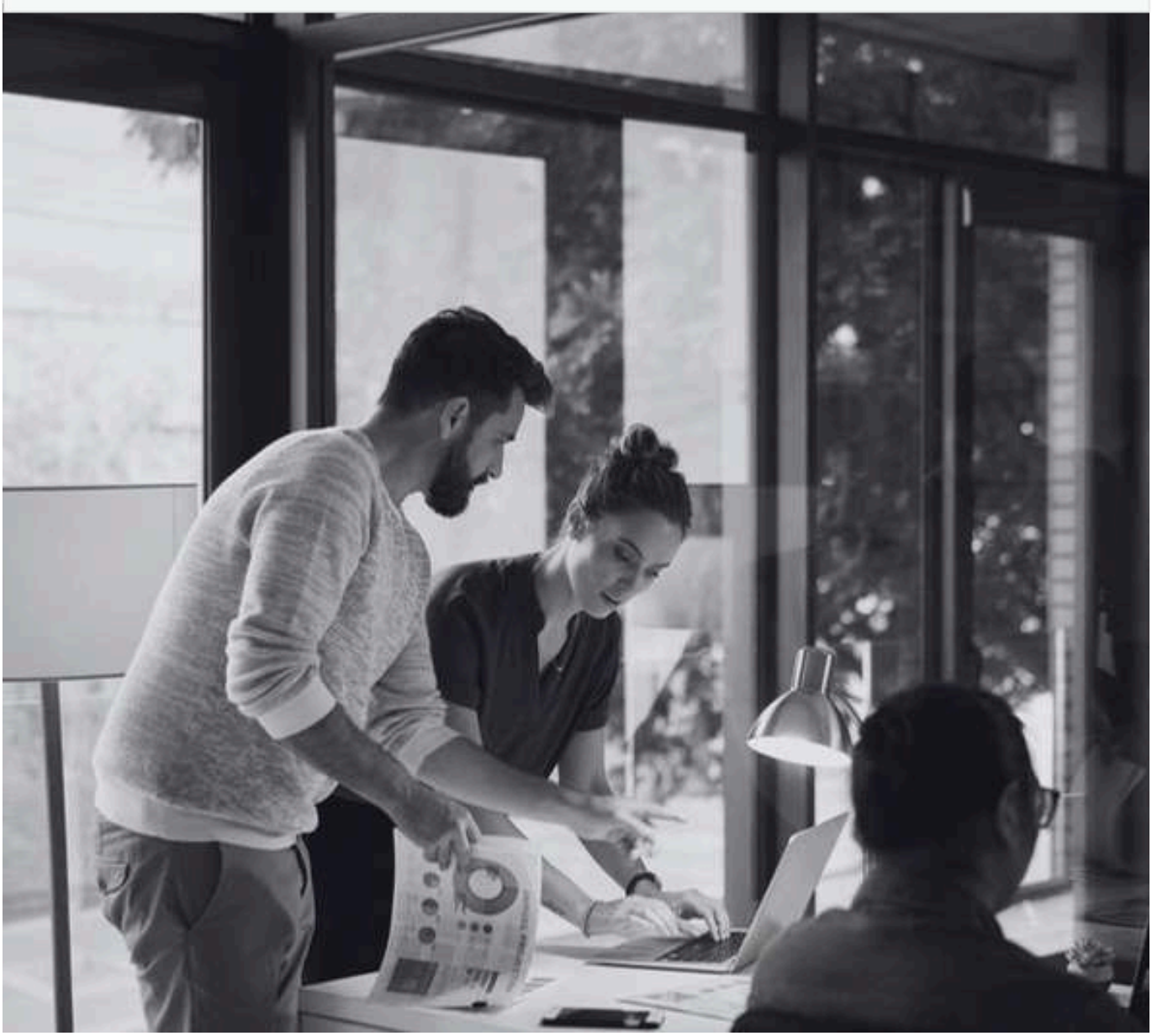
THE FUTURE COMPETITIVE ATTACK

Challenge the incumbent's total institutional value with verified access economics, fulfilment reliability and an evidence-based dossier. Do not claim "same drug, same result" from a shared international nonproprietary name. Explain the actual biosimilarity basis and approved scope without overstating it. A hospital should be able to select the product independently of any support offer.

WHAT MAKES THE FIRST FOOTHOLD DEFENSIBLE

Choose a hospital cluster where the future product's approved scope, supply capacity and affordability fit an identified need. Prepare a service that survives product neutrality and requires no proprietary lock-in. The measurable launch goal is qualified formulary evaluation and reliable fulfilment after clinical choice, not a promised conversion rate from a trial or education audience.

Neither an expected patent expiry nor an SEC recommendation fixes a lawful launch date. No India launch timing, interchangeability designation or discounted price is promised.



SELECTIVE ACCESS STRATEGY

WIN BY SOLVING ONE DIFFICULT HOSPITAL TASK





Today, “selective access player” can mean an authorised supply/access organisation, a hospital network or a product team serving a narrow segment of lawful supply. It is not evidence of a separate pembrolizumab manufacturer. A future approved product may adopt this posture after the entry gates are met.

FOCUS	PRACTICAL ADVANTAGE	TRADE OFF AND BOUNDARY
Regional pathology-to-oncology network	Coordinate externally ordered specimens, reports and a scheduled oncology review.	Requires laboratory and referral ownership; cannot fund tests to steer therapy.
Public hospital procurement pathway	Improve document completeness, authorised supply and scheduling against sanctioned access.	Tender and institutional rules govern; no prescriber-linked rebates or bid influence.
Patients travelling for infusion	Align the hospital-approved visit, required tests and travel information.	No guarantee of a dose on arrival; clinical clearance remains separate.
Cross-hospital toxicity handover	Make the treatment alert card and emergency-to-oncology transfer reliable.	Requires real clinical cover; a low-cost call centre cannot replace it.
One tumour-specific programme	Resolve a narrow recurring problem, such as perioperative handover or access renewal.	Smaller reach but clearer measurement; do not broaden beyond the approved pathway.

SELECTION RULE

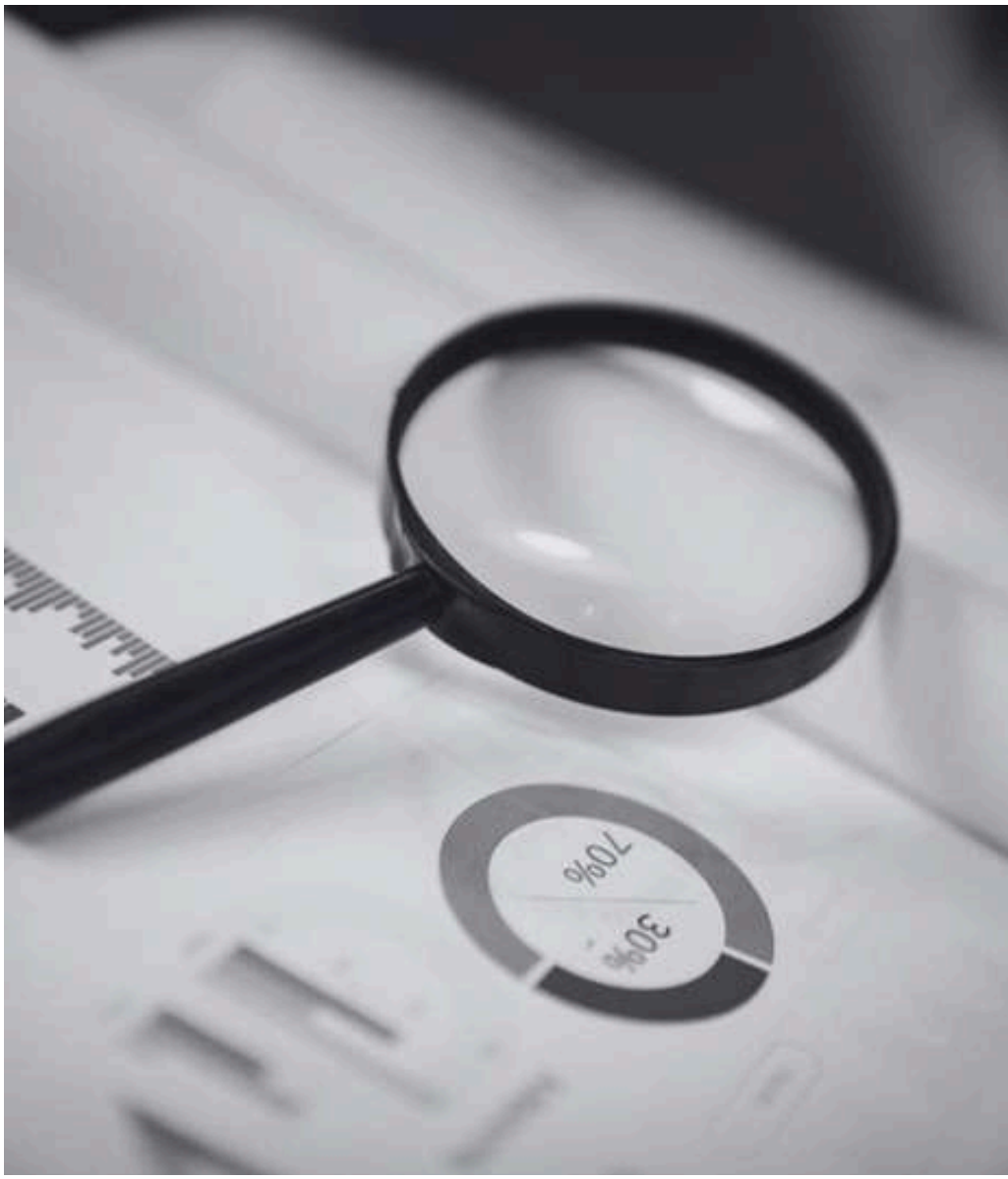
Rank a candidate segment on five factors: documented unmet task, clinical and emergency capacity, lawful product/access fit, hospital density and sustainable staff time. Reject it if the expected return depends on influencing the treatment choice, avoiding PV reporting, withholding support after a switch or selling patient data.

A PLAUSIBLE FOCUSED MOVE

A regional network may first standardise the external-report handover and one emergency re-entry record. It can then show fewer unresolved cases to participating hospitals. That creates an execution credential. It does not confer authority to recommend pembrolizumab, redirect patients to a sponsor hospital or claim better survival.

Choose this posture when broad national deployment would dilute service reliability. The competitive advantage is a repeatable local task completed well; it is not territorial exclusivity or ownership of a patient cohort.





FIELD FORCE AND KEY ACCOUNT EXECUTION

REPLACE THE EXTRA SALES CALL WITH A VERIFIABLE HOSPITAL ACTION



TRADITIONAL DETAILING	PROPOSED HOSPITAL EXECUTION	ROLE BOUNDARY
Discuss molecule evidence with an oncologist.	Medical team answers approval-specific questions; account team separately maps a hospital workflow gap.	No unsolicited off-label promotion or clinical recommendation from a navigator.
Repeat the brand message.	Demonstrate a fictional report, readiness and escalation episode to nursing, pharmacy and operations.	No real patient records in a sales demonstration.
Ask for prescribing support.	Ask the institution to assess workflow fit, burden and governance.	No prescription pledge, volume threshold or service-for-formulary exchange.
Sponsor an educational event.	Commission independent, disclosed scientific education with practical outputs and assessment.	No influence over individual tumour-board decisions.
Count calls and prescriptions.	Track institutional activation, trained roles, actual use and a separate aggregate commercial measure.	No individual patient-to-sales linkage.

THE ACCOUNT SEQUENCE

1. Obtain institutional permission to assess a documented process gap. 2. Meet the medical, nursing, pathology, pharmacy, operations and access owners. 3. Demonstrate the workflow with fictional data. 4. Complete legal, privacy, PV and Academy review. 5. Train staff and simulate an urgent event. 6. Start a small cohort. 7. Review workload and overdue handovers weekly. 8. Evaluate at day ninety.

A CREDIBLE OPENING

“We are presenting a hospital-controlled pathway for reports, access and symptom handovers. Your oncology team retains every treatment decision. It must remain useful when you choose another therapy or no immunotherapy. The first discussion is whether one unfinished task is important enough to test.”

Tumour boards remain clinician-led. Commercial personnel do not attend identifiable case deliberations to influence treatment or collect leads. A medical expert may contribute only through an authorised, disclosed scientific role under institutional rules. The key-account team works with institutional process owners and receives operational summaries, not patient cases.

No payments for prescriptions, patient recruitment, committee preference or access to clinicians. Training of representatives includes immediate forwarding of safety information to the designated PV route. [23–25]







PRIVACY AND PATIENT AUTHORITY

THE HOSPITAL KEEPS THE IDENTIFIABLE CARE RECORD

Design for data minimisation from the start. The hospital defines the care purpose and patient-facing service, and determines its legal role and responsibilities. Any service provider processes data only under a written, restricted mandate. Sponsors and field teams receive no patient-level programme records, contact lists, genomic reports or pseudonymised case exports.

CONTROL	OPERATING REQUIREMENT
Separate choices	Distinguish treatment consent, optional navigation consent, caregiver authority, communication preferences, research consent and any assistance-programme documentation. Refusal of support does not affect ordinary care.
Minimum record	Use a local episode identifier, authorised contact, clinical owner, relevant due tasks and factual reports. Keep source clinical documents within hospital-controlled systems.
Role-based access	Clinical team sees care information; coordinators see only what their task requires. No representative access, shared logins, personal messaging accounts or sponsor CRM integration.
Security and retention	Use encryption, audit logs, vendor controls, tested backup/recovery and a written retention/deletion schedule. Define breach response and grievance contacts before launch.
Sponsor output	Release only lawfully anonymised aggregates after disclosure-risk review. Suppress or combine small cells and rare combinations; a proposed minimum cell size of ten is a starting rule, not proof of anonymity.
Patient control	Explain purposes and recipients in the patient's language. Provide accessible correction, withdrawal and complaint routes, while explaining legal retention and safety-reporting obligations.



INDIA LEGAL TIMING MATTERS

DPDP commencement is phased. The November 2025 notification schedules the consent-manager provisions after one year and most core processing duties after eighteen months; the Rules also phase commencement. Do not call every DPDP duty already operative on 3 November 2026. Apply the existing IT/SPDI framework where relevant, medical confidentiality and contractual duties, and build to the forthcoming requirements. Recheck the legal position at activation. [26,27,31]

Pseudonymisation is not anonymisation. The sponsor must not be able to reconstruct a patient or prescriber-level treatment decision by combining hospital, tumour, date and product fields. Programme success cannot depend on such reconstruction.

Research and statutory safety reporting have separate purposes and governance. Neither may be concealed inside a general marketing consent. The October 2026 DPDP text-correction order does not itself make every core processing duty immediately operative. [34]

PHARMACOVIGILANCE AND MEDICAL ETHICS

URGENT CARE AND SAFETY REPORTING ARE PARALLEL OBLIGATIONS

A clinical call does not complete pharmacovigilance reporting, and a PV report does not provide emergency care. Every operator needs a written procedure for suspected adverse events, serious events, pregnancy exposures where relevant, medication errors, product complaints and suspected counterfeit supply. Do not wait for proof of causality before routing a suspected event. [25]

RESPONSIBILITY	REQUIRED ACTION
Hospital care team	Arrange clinical assessment immediately when needed and document the medical disposition.
Hospital PV lead	Capture the necessary safety facts, validate the reporting route and follow applicable PvPI/CDSCO and product-specific obligations. Preserve brand and batch traceability where available.
Programme operator	Train every contact role, record awareness time and promptly route reports. Proposed internal target: same-day forwarding, no later than 24 hours after awareness; emergency care is immediate.
Marketing authorisation holder	Meet applicable legal reporting and follow-up obligations through its designated safety function, with timelines determined by report type and law.
Oversight team	Reconcile intake and acknowledgements regularly; audit missed handovers. Never reward a low adverse-event rate or suppress inconvenient cases.

RESPECT THE AGGREGATE-ONLY SPONSOR BOUNDARY

No patient-level navigation dataset is supplied to pharma. Statutory individual-case safety reporting is handled through the hospital's separate PV process, with minimum necessary information and appropriate legal basis and notice. If that process requires case-level transfer to an MAH, the hospital's safety and privacy leads must approve that distinct route before activation. It is not a marketing-data exception and must not become a raw programme export. A service cannot promise absolute anonymity in a legally required safety report.



SPONSORSHIP MUST PASS AN INDUCEMENT TEST

UCPMP requires approval-consistent, substantiated promotion and regulates interactions and educational support. Medical ethics also constrain gifts, endorsements and commercial relationships. A neutral label alone does not make free staff, tests or infrastructure lawful. Assess the actual recipient, benefit, selection criteria, fair value, disclosure and procurement context. Reject any arrangement tied to prescriptions, product purchase, patient referrals or committee decisions. [23,24]

An independently reviewed service may be funded through an institutionally approved, transparent arrangement only after applicable legal and ethics review. No sponsor funds the clinical decision, no Academy endorses a brand, and no hospital loses essential care support because a prescribing target is missed.

MEASUREMENT



MEASURE CLOSURE BEFORE CLAIMING COMMERCIAL EFFECT

Freeze a data dictionary before enrolment. Use patient episodes, visits, tasks and hospitals as different units. Report numerator, denominator, observation window and missingness. A completed message is not a clinical review; a report received is not a treatment decision.

MEASURE	OPERATIONAL DEFINITION	INTERPRETATION
Primary process endpoint	Episodes with an oncology disposition documented by seven calendar days after the original decision-review due date / all enrolled decision episodes due by day 75.	The window is a measurement rule, not clinical permission to delay. Show timely, late and uncompleted separately.
Biomarker readiness	Episodes with all clinician-required reports interpreted by the original review date / episodes with those reports due.	No reward for unnecessary testing. Stratify by tumour and test.
Access decision time	Median and 90th-percentile days from complete application to written decision; also report time to achieve a complete application.	Do not hide document delays or call a denial a failure to sell.
Avoidable infusion disruption	Visits cancelled or delayed for adjudicated administrative reasons / planned visits due.	Clinical holds and patient choice reported separately, never penalised.
Safety routing	Reports requiring clinical escalation with acknowledged handover within the approved urgency interval / all such reports.	Report actual times, unresolved cases and outcomes; more reports may reflect better detection.
Review and transition	Due response/toxicity reviews with clinician disposition; transferred/stopped episodes with an acknowledged follow-up plan.	Assess each denominator separately. No automatic persistence target.
Adoption burden and equity	Active hospital weeks, staff minutes, failed contacts, language/digital barriers and patient-reported effort.	Measure non-digital access and unequal completion, not only averages.

Keep unreachable, withdrawn, transferred and deceased episodes visible in cohort accounting using lawful retained data; do not silently remove difficult cases. Late entrants not yet due are pending, not failures. Date changes retain the original date and reason. Zero means a verified count; blank means missing; a zero denominator is not applicable.

Clinical endpoints such as survival, response, severe-toxicity reduction or quality-of-life change require appropriate study design and longer follow-up. This pilot cannot establish a drug effect or improved cancer survival.





ATTRIBUTION AND COMMERCIAL ECONOMICS

USEFUL CARE DOES NOT AUTOMATICALLY CREATE SPONSOR RETURN

There are three separate questions: did the hospital use the service; did the targeted process improve; and did lawful commercial performance change? A positive answer to the first is not proof of the second or third. In a single verified-brand market, a near-total exact-molecule share would be an uninformative defence metric even if it could be measured.

COMMERCIAL PROXY	USE	LIMIT
Qualified formulary consideration	Document a formal institutional evaluation after lawful product availability.	Not a prescription or purchase commitment; service funding is separate.
Reliable institutional supply	Aggregate order fulfilment, stockouts and authorised supply complaints.	Supply demand is affected by clinical mix and budget.
Appropriate treated volumes	Use lawful hospital/market aggregates with a defined tumour, period and product universe.	No patient-level linkage; increased use is not necessarily improved care.
Future within-molecule share	Only after at least two lawful marketed products exist, define unit/value denominator and source.	No current challenger share or predicted displacement is assigned.
Adjacent regimen mix	A contextual signal when clinically comparable and lawfully measured.	Cannot imply equivalence or attribute clinical choices to support alone.

A fair comparison : Use matched hospitals or staggered activation with a pre-period, consistent eligibility and an analysis plan. Match or adjust for tumour/line, baseline delay, payer mix, public/private setting and testing availability. Record changes in price, assistance terms, supply, staffing, guidelines and competing activity. Report the change in intervention sites against the contemporaneous change in controls with uncertainty. Four sites are not enough for confident causal sales attribution.

Economics without a disguised sales target : Estimate actual staff time, training, content maintenance, governance, technology and evaluation costs. Divide by enrolled episodes and completed clinical decision episodes separately. Cost per additional timely decision uses a credible comparator-adjusted increase, not the raw number of reviews. If incremental benefit is zero or negative, report that; do not manufacture a favourable ratio.

Any sponsor return assessment uses separately obtained lawful aggregate contribution and programme cost. It must not set a minimum number of prescriptions for hospitals, nurses, patients or faculty.

No programme price, vendor fee or client-specific commercial terms are proposed in this playbook.





NINETY DAY PILOT

TEST ONE CLINICAL PATHWAY IN A SMALL HOSPITAL COHORT

Proposed feasibility design: four participating adult oncology hospitals in two matched pairs, with two starting the service and two continuing usual care during the evaluation window. Seek approximately 20–30 consecutive eligible decision episodes per hospital, subject to actual flow and consent. These are planning assumptions, not a powered sample or confirmed participation. No hospital, patient or Academy has been recruited.

PERIOD	WORK	REQUIRED OUTPUT
Days 1–15	Choose one tumour/line pathway and primary bottleneck. Review a feasible prior baseline. Confirm labels, hospital owners, comparison sites, independent Academy scope and governance.	Signed protocol and data dictionary; eligibility, outcome dates and safety rules frozen.
Days 16–30	Deliver education module 1; train staff with fictional cases, emergency handovers and a data-access test. Confirm usual-care safeguards at controls.	Observed competence; live contacts and backup; institutional launch approval.
Days 31–60	Activate intervention sites and enrol consecutively. Deliver education module 2. Review workload, contact failures and overdue actions weekly.	Auditable task completion and reason-coded delays.
Days 61–75	Deliver module 3; complete eligible due decision reviews. Review inclusion and missing data without changing targets to fit results.	Locked primary cohort; safety and neutrality audit.
Days 76–90	Allow the seven-day outcome window and data reconciliation; compare sites and interview staff/patients. Agree continuing clinical cover.	Go, refine or stop decision with limitations and an exit/continuity plan.

Comparison without withholding care : Controls retain all usual care, emergency information and clinical support. The service adds coordination, not access to necessary treatment. If matching is infeasible, use a pre-specified staggered rollout and model calendar-time effects. If neither design yields a credible comparator, label the result feasibility-only. Do not convert an uncontrolled before/after change into a causal claim.

Ethics classification before enrolment : The institutional ethics committee determines whether the work is service evaluation, research or a clinical trial. Obtain the necessary review, consent, permissions and prospective registration where applicable; do not self-declare exemption. The programme does not randomise drug selection, dosing or holds. Publish or disclose methods and unfavourable findings as agreed before launch. [28,32]

PILOT DECISIONS

SET THE GATES BEFORE SEEING THE RESULT

The following are proposed management thresholds, not regulatory requirements, clinical benchmarks or validated effect sizes. Freeze or revise them with the hospitals before enrolment. Safety, patient autonomy and lawful conduct override every commercial indicator.

GATE	PROPOSED STANDARD	ACTION IF NOT MET
Activation readiness	Every site has approved assets, named clinical and backup owners, tested emergency routes, consent and PV procedures.	Do not enrol at that site.
Critical safety and privacy	No unaddressed critical handover, unauthorised data disclosure or inducement concern. Review every serious incident independently.	Pause affected activity immediately; protect ongoing care; investigate before restart.
Primary process signal	At least 10 percentage points improvement in documented decision closure within the predefined window relative to the comparator; report uncertainty and case mix.	Refine if feasible; do not claim effectiveness from a small or unstable estimate.
Data quality	At least 95% of audited episodes contain the original due date, owner, source and disposition/status.	Repair definitions and capture; defer outcome claims.
Routine adoption	Both intervention hospitals use the worklist in at least 80% of active weeks without dependence on sales representatives.	Simplify or narrow the workflow before scale.
Staff burden	Proposed median incremental coordinator/nurse time at or below 20 minutes per active episode per week, with the upper tail and clinical time reported.	Reduce scope or add approved capacity; never shorten urgent care.
Neutrality and continuity	Support remains available after appropriate non-initiation, switch or stop; all active episodes have an exit owner.	Correct immediately; a sales gain cannot compensate.

THREE DECISIONS WITH DIFFERENT MEANINGS

Go to a larger controlled evaluation when safety, adoption, data quality and process improvement are credible and resources are sustainable. Refine when the service is safe but the task is poorly chosen, burdensome or weakly measured. Stop the model when it cannot deliver reliable clinical handover or lawful independence. Stopping the model must not abandon enrolled patients.

A commercially negative result can coexist with a useful service. It may justify hospital-led continuation with another funding model, not changing clinical rules to produce prescriptions.



CAPACITY TIMING AND THE MARKET DECISION

BUILD A HOSPITAL CAPABILITY BEFORE PROMISING A NATIONAL PROGRAMME

The legitimate first-mover advantage is learning: a trained clinical team, a working pathology interface, tested handovers and evidence of process improvement. It is not ownership of a tumour board, exclusive access to patients or a fabricated territory allocation. Another team can use the same opportunity and compete on execution.

CAPACITY IS A MEASURABLE CONSTRAINT

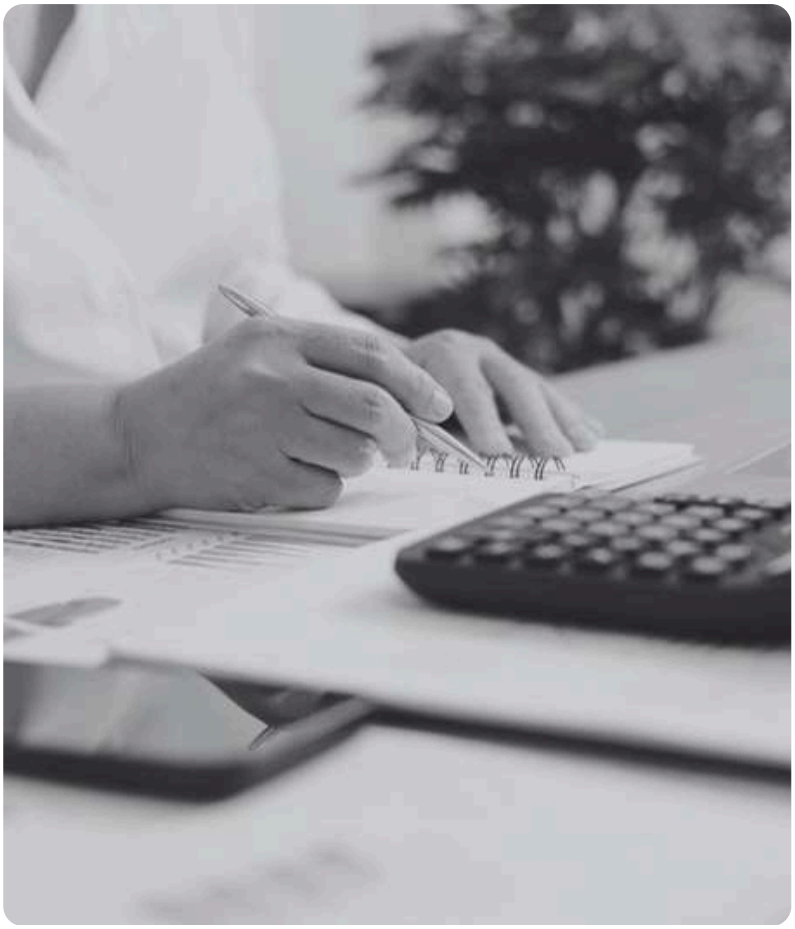
Publish the actual delivery calendar only after capacity is verified. Count protected hospital nurse/coordinator hours, clinician escalation cover, pathology support, independent reviewers, approved language versions and training slots. A sponsor budget is not clinical response capacity. No specific number of exclusive slots is claimed here.

Illustrative capacity check: 30 active episodes at a planning allowance of 15 coordination minutes each per week require 7.5 hours before enrolment, failed contacts, supervision and escalation. At 30 minutes the base requirement doubles to 15 hours. Size the cohort from observed workload and emergency cover; do not force staff to meet a marketing enrolment target.

WHY ACT NOW

The near-term work is useful before future biosimilar entry: hospitals can validate pathway needs, current pricing, independent review and reliable operations. Product entry remains uncertain. The scheduled November price implementation is a reason to check actual bills, not a pretext for a rushed launch. A credible first mover can arrive with evidence while others are still offering a concept.

YOUR POSITION	THE DECISION TO MAKE	YOUR POSITION
Originator leader	Which established hospital gap threatens institutional trust, and who owns fixing it?	**Originator leader**
Prospective challenger	Which approval, evidence and hospital-readiness capabilities must be complete before lawful entry?	**Prospective challenger**
Selective access player	Which narrow hospital task can your team serve reliably without distorting clinical choice?	**Selective access player**



Choose one pathway, one accountable hospital owner, one independent academic review route and one measurable decision gap. Test it under a bounded protocol. Decline it if the commercial case requires control of prescribing. This same generic opportunity is available to competing product teams where legally relevant. No company-specific mandate, prior distribution, adoption, endorsement or exclusivity is implied. The strategic choice is whether to build a credible hospital capability before a competitor demonstrates one.

INDIAN PRODUCT AND REGULATORY EVIDENCE

[1] MSD India. Product directory and Keytruda page. Current site checked 3 November 2026.
Primary manufacturer evidence of India brand presence. Detailed Keytruda content requires professional login; this review does not claim access to a complete current Indian PI.

[2] CDSCO. CT-18 approvals for import and marketing January 2020 to September 2026. Released 23 October 2026.
Primary India approval summary. Relevant entries 46, 69, 86, 113, 142, 161 and 174; PDF pages 20, 25–26, 29–30, 35, 41, 45 and 47. Entry 161 is for enfortumab, not a second pembrolizumab product. Not a full label.

[3] CDSCO. CT-21 approvals for manufacture and marketing January 2020 to September 2026. Released 23 October 2026.
Primary manufacturing approval list; no pembrolizumab entry found. Includes nivolumab records. Supports the qualified market conclusion, not an absolute claim about all unpublished approvals.

[4] CDSCO SUGAM. Approved Drugs Vaccines rDNA and Blood Products. Search performed 3 November 2026.
Search term Pembrolizumab returned 20 rows, including combination-partner products. Six exact-product rows identified MSD. The August 2026 HNSCC addition is visible. Some dates and indication summaries differ from the periodic CT-18 list; actual permissions and current PI control.

[5] CDSCO. Clinical trial permissions table. Reviewed through entries released 23 October 2026.
Selected pembrolizumab listings identify Sun, Intas, Enzene, Lupin and Kemwell/ASP200. These are CT records, not sale permissions. An MSD Phase IV record also must not be mistaken for a new brand or indication approval.

[6] CDSCO SEC Oncology. Recommendations of meeting dated 29 September 2026.
Primary development evidence: Sun's pembrolizumab Phase III protocol amendment. Does not demonstrate completed comparability, a brand launch or marketing approval.

DEVELOPMENT PRICING AND INSTITUTIONAL ACCESS

[7] CDSCO SEC Oncology. Recommendations of meeting dated 20 May 2026.
Primary development evidence for Hetero's comparative pembrolizumab study and protocol amendment. Trial participation does not establish commercial availability.

[8] CDSCO and Department of Biotechnology. Guidelines on Similar Biologics. 2016.
Regulatory framework for demonstrating similarity and marketing authorisation. Use the actual current approval conditions; a similarity claim is not automatic substitution authority.

[9] CDSCO. Draft revised Guidelines on Similar Biologics. 2025.
The retrieved document is explicitly a draft. It is not treated as a final operative replacement or as an approval for any pembrolizumab product.

[10] NPPA. Revised MRP of Non-Scheduled Anti-Cancer Drugs. Submissions through 2 November 2026; effective date 9 November 2026.
Primary company-reported price compilation. Entry 824, PDF page 59: MSD Keytruda 100 mg injection, pack 1, old and revised MRP INR 2,16,500. This is not a hospital net price, tender award or guaranteed patient expenditure.

[11] Department of Pharmaceuticals via PIB. Trade Margin Rationalisation on 137 Anti-Cancer Drugs. 17 October 2026.
Official announcement names pembrolizumab and specifies implementation from 9 November 2026. Broad potential reductions cannot be applied to an unchanged individual product entry.

[12] AIIMS New Delhi. Proprietary procurement notice for Inj Pembrolizumab 100 mg. Page updated 3 February 2026.
Primary institutional procurement evidence. A notice is not an award, national availability census, reimbursement guarantee or proof of competing manufacturers.

ACCESS CONTEXT AND TUMOUR GUIDANCE

[13] Government of India. Notification 09/2025-Customs GSR 102E. 1 February 2025.
Official customs notification names pembrolizumab assistance programmes Key-PAP 1.0 and KIRAN under MSD. Current eligibility and assistance terms require separate written verification.

[14] Zydus Lifesciences. Indian launch announcement for nivolumab biosimilar Tishtha. 22 January 2026.
Primary company statement for adjacent-molecule launch and dated prices. Promotional claims of population benefit and relative affordability are not adopted as independent facts or pembrolizumab savings.

[15] DHR and DGHS Ministry of Health and Family Welfare. Evidence based Guidelines for Lung Cancer Treatment. Released February 2026.
Current Indian national evidence-based lung guidance retrieved. Relevant questions include driver-negative advanced NSCLC, perioperative treatment and individualised dosing. Lower-dose pembrolizumab consideration is conditional, very low certainty, and requires explicit documentation and informed consent; it is not label equivalence.

[16] ASCO. Therapy for Stage IV NSCLC Without Driver Alterations Living Guideline version 2026.3.2. Updated 28 May 2026.
Official current living-guideline record and indexed summary reviewed. International clinical context only; no assumption that all listed regimens are approved or available in India. The complete download was not openly retrievable in this review.

[17] ESMO. Guidelines news and living guideline version register. Checked 3 November 2026.
Official register identifies early/locally advanced NSCLC version 1.3 August 2026 and metastatic breast cancer version 2.0 August 2026. Used for currency and tumour-specific review requirements, not to infer Indian approvals or reproduce proprietary algorithms.

[18] ESMO. Gynaecological cancer guidelines register. Cervical cancer guideline dated 24 September 2026.
Official current cervical guideline listing; Lorusso and colleagues, ESMO Open 2026, article 108364. Establishes the need for a current tumour-specific review. Not a substitute for Indian approval wording.

SAFETY AND PROFESSIONAL CONDUCT

[19] MSD Merck. KEYTRUDA US Prescribing Information. Retrieved version with October 2026 indication updates.
Authoritative international safety reference, particularly severe/fatal immune-mediated reactions, delayed events and monitoring. It is explicitly a US label. US indications, doses and administration routes are not imported into Indian promotional claims.

[20] US FDA. Traditional approval and revised TMB-high indication for pembrolizumab. 16 October 2026.
Primary US regulatory update changes the TMB threshold to at least 13 mutations/Mb. Included to illustrate why jurisdiction and version control matter; does not establish an Indian tissue-agnostic indication.

[21] Schneider BJ and colleagues. ASCO immune-related adverse events guideline update. JCO 2021;39:4073–4126.
Primary professional safety guideline. Supports multidisciplinary assessment and clinician-directed management. Use the corrected current article and local protocol; this playbook does not reproduce a treatment or steroid-dosing algorithm.

[22] Brahmer JR and colleagues. SITC guideline on immune checkpoint inhibitor related adverse events. 25 June 2021.
Primary guideline publication, JITC 9:e002435. Supports broad organ-system vigilance and clinical escalation. Its age is explicit; supplement with current labels, safety updates and hospital protocols.

[23] Department of Pharmaceuticals. UCPMP 2024 updated as on 1 September 2025.
Official promotion and professional-interaction framework. Relevant to approval-consistent claims, pre-approval promotion, educational sponsorship, benefits and disclosures. A neutral service description alone is not legal clearance.

[24] National Medical Commission. Code of Medical Ethics Regulations 2002 as published on the current rules portal.
Primary professional ethics source for confidentiality, endorsements and industry relationships. Read with the 2023 abeyance notification and any later applicable state/institutional rules.

PATIENT SAFETY PRIVACY AND RESEARCH

[25] Indian Pharmacopoeia Commission and CDSCO. Pharmacovigilance Guidance for Marketing Authorization Holders version 2.0. 2024.
Primary India PV framework. The playbook's same-day/24-hour internal routing target is a proposed service rule, not a substitute for category-specific statutory reporting requirements.

[26] MeitY. GSR 843E commencement notification for the DPDP Act. 13 November 2025.
Official phased commencement: specified provisions immediately, consent-manager-related provisions after one year, most core processing provisions after eighteen months. Recheck operative dates and amendments at deployment.

[27] MeitY. Digital Personal Data Protection Rules 2025 GSR 846E. 13 November 2025.
Official Rules, with phased commencement under rule 1. Supports forward design for notice, security and accountable processing; not a claim that every rule is already effective at the cutoff.

[28] ICMR. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. 2017.
Primary Indian research-ethics framework. Institutional review determines the status of the proposed evaluation and applicable consent, registration and transparency duties. Clinical service activity must not conceal research.

[29] National Health Authority. Is cancer treated under PMJAY. Official support guidance, checked 3 November 2026.
Explains staged/package pre-authorisation. It does not verify nationwide pembrolizumab reimbursement, a particular patient entitlement or a current state package rate.

[30] Haanen J and colleagues. ESMO guideline for management of immunotherapy toxicities. Ann Oncol 2022;33:1217–1238.
Primary professional guideline; accessible author guideline copy reviewed at https://serio-registry.org/sites/default/files/2023-10/Haanen_ESMO_Guidelines.pdf. Supports diagnosis, differentials and specialist management; no universal service treatment algorithm is supplied.

LEGAL TRANSITION AND EVIDENCE LIMITS



[31] Government of India. IT Reasonable Security Practices and Sensitive Personal Data or Information Rules. GSR 313E, 11 April 2011.
Official existing privacy/security framework, including health-related sensitive information. Applicability and transition must be assessed for the hospital and service provider rather than assuming the DPDP framework displaced all duties immediately.

[32] CDSCO. New Drugs and Clinical Trials Rules 2019 and published amendments register.
Primary statutory reference route. Any activity classified as a clinical trial must follow the operative rules, permissions, ethics and registration requirements; a marketing playbook cannot authorise it.

[33] NMC. Professional Conduct Amendment Regulations dated 23 August 2023.
Primary notification holds the 2023 conduct regulations in abeyance and adopts the 2002 regulations. Do not cite the unimplemented 2023 text as if fully operative.

[34] MeitY. DPDP Removal of Difficulties Order 2026 SO 5458E. Dated 5 October; Gazette issue 6 October 2026.
Primary text correction concerning guardianship wording and data audits. It does not replace the phased commencement notification. Included to preserve the November 2026 legal cutoff.

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STRATEGIC OPPORTUNITY & CTA

The decision for a pembrolizumab leadership team is simple: Will you remain focused on product positioning, evidence and access discussions, or become the partner that helps hospitals complete the critical decisions between biomarker results, treatment readiness and toxicity review?

Pembrolizumab doesn't need another molecule-awareness campaign. It needs a strategy that owns the biomarker-to-treatment-to-toxicity review pathway—helping hospitals close report-to-decision gaps, resolve access barriers, verify infusion readiness, and ensure new or worsening symptoms reach the right clinical team.

Old rule: Win the product consideration.
New rule: Own the hospital handovers that make the care pathway work.

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The next winning pembrolizumab partner will become the hospital's oncology pathway-enablement partner—connecting pathology, oncology, pharmacy, access teams and infusion services so that every critical handover has a clear owner and documented next step.

The opportunity is to make dependable hospital execution the basis of institutional preference—not another product claim, price promise or patient-enrolment target.

Next Steps
If you would like to explore how these ideas can be adapted to your market position and institutional strategy, we would be happy to discuss them further.
Get in touch with our team to schedule a 30-minute Pembrolizumab Hospital Pathway Diagnostic and identify your competitive position, highest-priority hospital workflow gap, first pilot cluster, accountable clinical stakeholders, and a focused 90-day implementation plan.





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