HERMS WHITE PAPER | NOVEMBER 2026

Cell and Gene Therapy Readiness in the Gulf

From Approval to Patient Infusion

HERMS Consultancy DMCC

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Cell and Gene Therapy Readiness in the Gulf:

From Approval to Patient Infusion

A practical framework for turning product authorization into safe, funded and traceable patient access.

THE CENTRAL ARGUMENT

Approval is a product milestone. Readiness is a patient-level capability: the right treatment, the right centre, an intact product pathway, confirmed funding and accountable follow-up.

HERMS Consultancy DMCC

Dubai, United Arab Emirates

Evidence review: 5 November 2026

For health-system leaders, specialist providers, payers, manufacturers and market-access teams. This white paper offers a strategic and operational framework, not a clinical protocol or a product-specific regulatory opinion.

Executive summary

The Gulf's cell and gene therapy opportunity should be judged by completed, safely governed patient pathways rather than by approval announcements alone. This paper proposes a readiness model that connects regulatory permission, funding, clinical capability, product integrity and follow-up through explicit decision gates.

Regional milestones already span distinct stages: Bahrain announced CASGEVY approval in December 2023; Saudi Arabia reported approval in January 2024; and Abu Dhabi announced introduction of the therapy in March 2025. NHRA [2] Saudi Press Agency [1] DoH Abu Dhabi [3] These are meaningful developments, but none is a substitute for a current, patient-specific authorization and delivery record.

Five priorities for decision-makers

Separate permission from capability: keep product authorization, facility licensing, manufacturer qualification, patient funding and clinical eligibility as different approvals.

Design around the modality: autologous CAR-T, ex vivo gene-edited stem cells and in vivo gene therapies require different operational pathways. The paper uses product guidance and international standards to illustrate these differences. FACT-JACIE [11] SFDA CASGEVY guide [12] EMA CASGEVY information [13] SFDA Zolgensma guide [14]

Protect irreversible decisions: no schedule or commercial commitment should override the documented readiness checks required before preparative treatment, product thawing or administration.

Fund the complete episode: agree who pays for diagnostics, collection where applicable, manufacturing, treatment, complications, travel and follow-up before committing the patient.

Measure access and attrition: track referral-to-decision and decision-to-infusion intervals alongside patients deferred, declined, lost to follow-up or unable to proceed.

PROPOSED READINESS RULE

A patient is ready to proceed only when every applicable safety-critical gate is closed with evidence and named sign-off. Do not average a failed gate into an overall "green" score.

Reading guide

Regional evidence and modality differences establish the context. The core sections then cover authorization and funding, patient and centre readiness, product logistics, follow-up and operating economics; the final sections provide a 90-day mobilization plan and a practical readiness checklist.

Scope: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the UAE. The country snapshot is selective evidence, not a complete product register or a ranking of national readiness. International guidance is explicitly distinguished from Gulf requirements.

The Gulf landscape: progress is not uniform readiness

The evidence below records different types of progress, not comparable national performance. Publication dates are retained so that a historical approval, a research programme or a single treated patient is not presented as proof of current routine availability.

Market	Verified evidence	Readiness interpretation
Saudi Arabia	SFDA approval of CASGEVY was reported on 8 January 2024. KFSHRC reported more than 200 CAR-T patients treated since 2020 in October 2025. Saudi Press Agency [1] KFSHRC [4]	KFSHRC explicitly described its first locally manufactured CAR-T treatment as part of an initial clinical trial. Do not equate local trial manufacture with routine commercial authorization. KFSHRC [4]
United Arab Emirates	DoH announced CASGEVY introduction through ADSCC on 28 March 2025, with the first patient scheduled to begin in April. The announcement reports EDE market authorization. DoH Abu Dhabi [3]	The announcement also mentions insurance coverage subject to regulations and standards; it does not establish universal coverage, patient-specific approval or completed infusion at the announcement date. DoH Abu Dhabi [3]
Bahrain	An NHRA release dated 2 December 2023 announced CASGEVY approval for sickle cell disease (SCD) and transfusion-dependent beta-thalassemia. NHRA [2]	The release does not specify treatment capacity, launch arrangements or patient-level coverage. Those items require separate verification. NHRA [2]
Oman	Oman Observer, reporting ONA, described locally prepared and engineered CAR-T treatment at University Medical City on 12 May 2026. Oman Observer / ONA [6]	The report does not identify the authorization route or whether the treatment was research or routine care. Do not infer a licensed commercial manufacturing platform. Oman Observer / ONA [6]
Qatar	HMC's Cancer Research Institute page describes preclinical CAR-transduced T-cell and NK-cell work and a translational research programme. Hamad Medical Corporation [5]	This page supports research capability, not a verified inventory of commercial CAR-T products or active routine treatment slots. Hamad Medical Corporation [5]
Kuwait	IU Health documented a Kuwaiti patient travelling for CAR-T therapy on 5 June 2024, including travel and accommodation support. IU Health [7]	This is evidence of one cross-border pathway, not evidence that Kuwait lacks domestic capability or a statement of current national coverage. IU Health [7]

Evidence gaps are not negative findings. Before launch or referral, obtain current product status, treatment-site scope, capacity, payer eligibility and the lawful access route directly from the relevant parties.

Three modalities, three operating pathways

A single “cell and gene therapy” checklist is insufficient. FACT-JACIE standards address cellular-therapy collection, processing and administration, whereas the cited CASGEVY and Zolgensma materials show product-specific requirements that cannot be transferred indiscriminately between modalities. FACT-JACIE [11] SFDA CASGEVY guide [12] SFDA Zolgensma guide [14]

Modality	Pathway and dependency	Readiness emphasis
Autologous CAR-T	Patient collection, manufacture, product return, preparative treatment where specified, infusion and toxicity monitoring. KFSHRC describes the collection, modification and reinfusion model. KFSHRC [4]	Maintain patient-product linkage across every handoff. Prepare for cytokine release syndrome and neurological toxicities according to the current label and local programme. FACT-JACIE [11] FDA REMS announcement [15]
Ex vivo gene-edited stem cells	Mobilization and apheresis of haematopoietic stem and progenitor cells (HSPCs), manufacture, product return, myeloablative conditioning and infusion. CASGEVY is an example, not a generic protocol. SFDA CASGEVY guide [12] EMA CASGEVY information [13]	Confirm transplant suitability, rescue-cell availability and the complete product dose before the relevant irreversible step. Address fertility and long-term follow-up. EMA CASGEVY information [13]
In vivo gene therapy	The product is administered directly; the cited Zolgensma pathway does not require patient-cell collection and return. Its guide specifies pre-treatment assessment and post-infusion monitoring. SFDA Zolgensma guide [14]	Product-specific antibody testing, organ assessment, medicines, laboratory monitoring and specialist escalation can remain essential even without a patient-specific manufacturing loop. SFDA Zolgensma guide [14]

What should be common

Use a common governance structure for eligibility, consent, funding, product receipt, adverse-event escalation and follow-up accountability. Attach a controlled modality and product addendum rather than forcing all therapies into the same timings, temperatures, tests or staffing model.

What should remain separate

Allogeneic cell products, investigational constructs and locally manufactured products need their own donor, manufacturing, release and authorization assessments. A successful treatment or an accredited clinical service should not be treated as proof that a different construct, indication or manufacturing site is authorized.

OPERATING IMPLICATION

Choose the first service by its complete pathway requirements and available capability, not by the attractiveness of the product announcement. An imported commercial therapy programme and a local manufacturing programme are different investments.

Authorization and funding: close the correct gates

The UAE illustrates the need to distinguish product and service permissions: EDE provides a marketing-authorization route for pharmaceutical and biological products, while DHA’s HSCT standard separately sets service licensing and accreditation requirements within its scope. EDE [8] DHA [9] The operational recommendation is to maintain a product–indication–site permission matrix rather than a single “approved” field.

A jurisdiction-specific permission record

Product route: record the authorized indication, current local label, age and other eligibility limits, marketing-authorization holder and any lawful special-access or trial route. Record the effective version and who verified it.

Service route: document the facility licence, scope of practice, required accreditations, specialist privileges and any product-specific manufacturer qualification. Do not assume one substitutes for another.

Import and release route: establish the applicable permissions for starting material, finished product, customs clearance and release or acceptance. Assign responsibility for each handoff before scheduling shipment.

Research route: keep ethics approval, sponsor responsibilities, investigational supply, consent and reporting separate from commercial access. A trial does not become routine care because treatment occurs in an established hospital.

SCOPE CHECK THAT MATTERS

DoH's January 2026 regenerative-medicine standard explicitly excludes gene therapies and more-than-minimally-manipulated cell therapies. Do not use that document alone as the authorization basis for CAR-T or gene-edited cell therapy. DoH Abu Dhabi [10]

A complete funding decision, not a drug-only approval

Recommended financial authorization should cover the medicine and the care episode, including diagnostics, collection where applicable, preparative treatment, hospitalization, complications and follow-up. It should identify coverage exclusions, expiry dates, patient contributions, cancellation terms and who carries the cost of collection or manufacture if infusion cannot proceed.

DoH's CASGEVY announcement mentions insurance coverage under applicable regulations and standards, but does not publish universal entitlement or individual policy terms. DoH Abu Dhabi [3] A programme should therefore verify the patient, product, provider and funding route together before accepting a funded treatment slot.

This paper does not establish a GCC-wide reimbursement entitlement, a common authorization pathway or a regulatory review-time guarantee. Each live case requires current local confirmation.

Patient and centre readiness: make accountability explicit

For CASGEVY, the EU product information calls for an authorized centre and physicians experienced in transplantation and beta-haemoglobinopathies, and identifies fertility implications of myeloablative conditioning. EMA CASGEVY information [13] These are useful product-specific benchmarks; the applicable Gulf label and local service requirements remain controlling.

The patient readiness conference

Before reserving an irreversible treatment step, the multidisciplinary team should document diagnosis and indication, alternatives, expected benefit and uncertainty, current organ and infection assessment, clinical fitness, consent and caregiver arrangements. For paediatric patients, the programme should address age-appropriate communication and the applicable consent or assent process.

Recommended counselling should explain the complete journey, possible manufacturing or scheduling failure, treatment-related risks, fertility considerations where relevant, the possibility of no durable benefit and the follow-up burden. Provide understandable Arabic or other preferred-language materials and a named route for questions, rather than treating a signature as proof of comprehension.

Accountable function	Minimum evidence to close the gate
Clinical programme lead	Eligibility and fitness decision; current patient assessment; prescribing and escalation ownership; documented reason for proceeding or deferring.
Collection / laboratory lead	Qualified collection pathway where required; identity checks; product handling competency; validated storage and contingency arrangements.
Nursing / pharmacy lead	Product-specific training; administration workflow; verified availability of required medicines, supplies and monitoring capability.
Critical-care / specialist services	Documented escalation and transfer pathway; relevant on-call cover; evidence that emergency simulations have been completed.
Case manager / payer liaison	Funding approval; travel and caregiver plan; patient contact route; post-discharge appointments and receiving-care arrangements.

Accreditation is scoped evidence

DHA's HSCT standard requires hospital and laboratory accreditation before service commencement and FACT or equivalent accreditation of the clinical HSCT service within 24 months of licence activation. DHA [9] FACT-JACIE also distinguishes transplant programmes from immune-effector-cell-only programmes, with different applicable accreditation pathways. FACT-JACIE [11]

These are not a universal timetable or accreditation rule for every Gulf gene-therapy service. Verify the exact jurisdiction, licence, clinical scope and current standard before applying them.

Product integrity: connect manufacture to the bedside

FACT-JACIE defines chain of identity as the enduring association of product identifiers throughout the lifecycle, and chain of custody as auditable documentation of guardianship from origin to final disposition. FACT-JACIE [11] Both are needed; a shipment-location record alone does not establish patient-product identity.

A traceable end-to-end record

The proposed record links patient identifiers, collection identifiers where applicable, manufacturer order, batch or lot, release documentation, courier handoffs, temperature evidence, site receipt, storage location, administration and final disposition. Every discrepancy needs an owner, disposition and documented closure rather than an informal explanation.

Control point	Evidence and decision
Before collection / ordering	Reconcile patient identity and order; establish the authorized route, slot and funding commitment; confirm contingency ownership.
Shipment preparation	Use product-specific packaging and qualified transport arrangements; verify documents, receiving availability and disruption procedures.
Site receipt	Reconcile identity, quantity, integrity, transport conditions, release documents and storage capability; quarantine unresolved discrepancies.

Control point	Evidence and decision
Before preparative treatment	Verify all product-specific prerequisites, current patient fitness and capacity. Apply the local label; do not infer readiness from an expected delivery date.
Before thawing / administration	Verify patient-product match, order, full dose where applicable, expiry and trained staff; document product acceptance and clinical authorization separately.

An important product-specific dependency

EU CASGEVY information states that conditioning must not begin until the complete dose has arrived at the authorized treatment centre and backup rescue-cell availability is confirmed. EMA CASGEVY information [13] The Saudi handling guide requires patient-identifier reconciliation and two-person bedside checks before each vial, as well as product-specific cryostorage and thaw-to-infusion controls. SFDA CASGEVY guide [12]

These examples show why a general logistics service-level agreement is insufficient. The readiness plan should translate the current local label into controlled checkpoints without copying temperatures, time limits or release criteria from one product to another.

HARD STOP

An unresolved identity mismatch, product-integrity concern or missing critical prerequisite should trigger a hold and escalation. Neither sunk cost nor a booked bed is evidence that the product can safely be administered.

Infusion is a transition, not the end of the service

The FDA's June 2025 removal of REMS for six listed BCMA- and CD19-directed autologous CAR-T products did not remove adverse-event reporting or manufacturer postmarketing safety studies. FDA REMS announcement [15] It is a US action, not a blanket relaxation of Gulf facility, manufacturer or product-specific safety obligations.

Maintain product-specific acute safety capability

CAR-T programmes must interpret the current product's toxicity warnings and local care requirements rather than rely on historical US certification rules; the FDA announcement still identifies cytokine release syndrome and neurological toxicities in product labeling. FDA REMS announcement [15] The recommended local readiness evidence is a practiced response pathway, appropriate specialist cover and confirmed availability of required rescue treatment under the applicable protocol.

The Saudi Zolgensma risk-minimization guide illustrates a different burden: it specifies pre-treatment assessment and clinical and laboratory monitoring for at least three months after infusion, including liver-related safety monitoring. SFDA Zolgensma guide [14] A programme should not describe in vivo therapy as operationally simple merely because apheresis and patient-specific cell manufacture are absent.

Build follow-up before accepting the patient

Clinical ownership: identify the treating lead, the long-term receiving clinician and the escalation route for suspected delayed toxicity.

Continuity: agree where tests occur, who reviews results, how missing visits are escalated and how paediatric patients transfer to adult care.

Cross-border care: confirm lawful data sharing, travel feasibility, emergency access, payment responsibilities and handover acceptance before the patient returns home.

Patient support: give a treatment summary, product identifier, emergency contact and understandable safety instructions, with a recovery and caregiver plan.

Do not impose one follow-up duration on all products

FDA guidance recommends a risk-based approach and explicitly states that not all gene therapies require long-term follow-up observations. FDA LTFU guidance [16] The EU CASGEVY information specifies annual monitoring for 15 years, illustrating a product-specific commitment rather than a universal GCC rule. EMA CASGEVY information [13]

GOVERNED EVIDENCE, NOT AUTOMATED CLINICAL AUTHORITY

Digital systems can reconcile documents, flag missing evidence and support scheduling or reminders. Patient eligibility, product acceptance, release decisions and clinical treatment remain with appropriately authorized human decision-makers.

Economics and capacity: finance the whole pathway

This paper recommends an episode-based planning model rather than a drug-price-only budget. It does not estimate a regional market size, treatment price, return on investment or savings claim; those require product-, payer- and population-specific data.

Build the denominator before the budget

Start with clinically assessed candidates, not disease prevalence or a promotional market forecast. Model how many patients are likely to be eligible, funded, able to undergo collection where relevant, successfully supplied, clinically fit at the scheduled date and ultimately infused; allow the order of these stages to vary by product.

Budget component	Decision that should be explicit
Assessment and preparation	Who funds diagnostic confirmation, specialist assessment, counselling, fertility preservation where relevant and repeat testing?
Collection and manufacture	Who pays for repeat collection, failed manufacture, cancellation, rescheduling and unused patient-specific product?
Treatment and complications	Which inpatient, critical-care, laboratory and supportive-care costs are included, excluded or capped?
Travel and recovery	Who covers visas where needed, accommodation, caregiver support, local transport and an extended stay?
Follow-up and evidence	Who funds long-term clinical monitoring, data entry, registry participation and care after a patient changes payer or country?

Design contracts around measurable events

Where legally and commercially appropriate, payment milestones can be linked to verifiable events such as supply acceptance, infusion or an agreed clinical outcome. An outcomes-linked contract should define the population, endpoint, measurement window, missing-data rules, adjudicator and financial consequence before treatment; clinical judgement must remain independent of payment incentives.

Separate operational failure from lack of clinical response. A manufacturing failure, a patient becoming unfit before infusion, a missing outcome assessment and a verified non-response should not be treated as the same contractual event.

Capacity is a pathway constraint

For planning purposes, model capacity as the minimum of the applicable bottlenecks: funded patients, diagnostic work-up, collection slots, manufacturing allocation, treatment beds, specialist cover and follow-up capacity. Validate the forecast against actual completion times and disruption scenarios before adding new indications or sites.

INVESTMENT PRINCIPLE

Local manufacturing should be evaluated as a separate business and regulatory case. Demonstrating clinical delivery capacity does not by itself establish process comparability, commercial manufacturing approval or sustainable production economics.

A 90-day readiness mobilization plan

The following is a proposed planning cadence, not a promise of licensure or first infusion within 90 days. The purpose is to produce an evidence-backed go, hold or redesign decision for a defined product, indication, site and payer route.

Planning period	Work package	Exit evidence
Days 1–30	Define the first pathway; confirm legal and product scope; map patient demand and capacity; appoint clinical, quality, access and logistics owners.	Approved scope; source-controlled permission matrix; baseline gaps; named decision owners and funding assumptions.
Days 31–60	Close priority SOP, training, payer, supplier, storage, data and referral gaps. Reconcile product-specific prerequisites and long-term ownership.	Documented competency; executable agreements; controlled workflows; funded remediation plan for unresolved gaps.
Days 61–90	Run end-to-end simulations, including delay, mismatch, patient deterioration and emergency escalation. Review evidence before accepting the first live case.	Signed simulation report; closed critical deviations; approved capacity; independent readiness review and decision record.

A small dashboard with defensible definitions

Measure	Recommended definition and interpretation
Referral-to-decision time	Days from receipt of a complete referral to documented multidisciplinary decision. Report median, 90th percentile and incomplete referrals separately.
Decision-to-infusion time	Days from documented eligibility decision to infusion, reported by product and route. Separate payer, manufacturing and clinical delay reasons.
Infusion conversion	Infused patients divided by patients judged eligible in a defined entry cohort; state follow-up window and show pending cases separately.
Pre-infusion attrition	Eligible patients who do not reach infusion, classified by funding, clinical deterioration, supply, withdrawal or other documented reason.
Traceability and follow-up	Critical identity/custody deviations; unresolved deviations; completed follow-up assessments divided by assessments due, with deaths and transfers identified.

Use weekly operational review and monthly governance review initially. Targets should be set from the local baseline and applicable obligations, not invented regional benchmarks; preserve required safety-reporting timelines independently of dashboard cycles.

Abu Dhabi's Jawda guidance already requires defined HSCT quality reporting for in-scope providers, illustrating why a programme dashboard must coexist with mandated reporting rather than replace it. DoH Jawda guidance [17]

Readiness checklist and leadership agenda

This checklist is a proposed management tool, not an accreditation instrument or validated readiness score. Assess each item as complete, incomplete or not applicable with a documented rationale, evidence reference, owner and review date.

Gate	Evidence needed for a "complete" decision
Lawful access	Verified product/indication route; applicable permissions; facility scope; current label and risk-management obligations.
Patient eligibility	Multidisciplinary decision; updated fitness; informed consent; alternatives discussed; caregiver and fertility considerations where applicable.
Episode funding	Patient-specific approval and payment responsibilities, including complications, cancellation, travel and follow-up.
Centre capability	Qualified team; current privileges; relevant accreditation; product training; equipment readiness and emergency cover.
Supply and identity	Confirmed manufacturing or supply pathway; reconciled identifiers; qualified transport; receipt and storage acceptance; discrepancy controls.

Gate	Evidence needed for a “complete” decision
Preparative treatment	All product-specific prerequisites met; patient reassessed; required product and rescue arrangements verified; clinical sign-off.
Infusion and escalation	Correct patient and product; current order; trained team; required medicines and monitoring; documented escalation authority.
Long-term continuity	Named clinical owner; funded monitoring plan; patient contacts; registry/reporting duties; accepted cross-border handover if relevant.

What leadership should commission next

Commission one integrated readiness dossier for the first priority pathway, with clinical, regulatory, quality, finance and supply-chain ownership. Require a documented no-go decision whenever a safety-critical prerequisite is unresolved, and retain the reasons so the organisation can distinguish remediable delay from inappropriate treatment.

For a specialist advisory team such as HERMS, the appropriate role is to structure source verification, requirements mapping, stakeholder alignment and readiness evidence. It is not to replace the regulator, manufacturer release function, payer decision or treating team, and this paper does not claim that HERMS operates clinical services or has validated patient outcomes.

CONCLUSION

The next measure of Gulf progress should be the ability to deliver an accountable patient pathway: lawful access, appropriate selection, complete funding, reliable product handling, safe administration and continuity of care. Approval opens the pathway; readiness makes it usable.

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Method and limitations

This is a targeted public-source review and an operational synthesis, not a systematic clinical review, live treatment-centre audit or exhaustive national authorization inventory. Sources were selected for relevance to product approval, regional delivery milestones, clinical-service standards and safety controls. Historical announcements establish what was reported on their publication dates, not present-day capacity or eligibility.

Recommendations, readiness gates, planning periods, economic questions and dashboard definitions are analytical proposals. No patient-level dataset, proprietary pricing, clinical outcome analysis or quantitative readiness validation was undertaken. Verify current local documents and obtain qualified clinical, regulatory and legal review before implementation.

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