ABU DHABI HELM CLUSTER ACTIVATION 2026

Cell & Gene Therapy

A strategic sub-advisory proposal from EY and MADE Scientific to operationalize the UAE's first commercial-scale ATMP manufacturing ecosystem and establish Abu Dhabi as the MENA hub for advanced therapy innovation.

WORKSTREAM
CGT & Strategic Partnerships

ENGAGEMENT
2026 Implementation Phase

SUBMITTED BY
EY × MADE Scientific

Part 1: Letter of Transmittal

Department of Health – Abu Dhabi Attn: Dr. Asma Al Mannaei, Executive Director – Health Life Sciences Sector Project Manager: Dr. Mohammed Al-Bitar, Advisor – Research and Innovation

Re: Proposal for External Consulting Services, Activation of Abu Dhabi's Health & Life Science Hub (HELM Cluster), 2026 Implementation Phase, **Workstream 2 (Cell & Gene Therapy Development) and Workstream 3 (Strategic Partnerships and Global Positioning)**

Dear Dr. Al Mannaei and members of the DOH Project Team,

Ernst & Young, in formal consortium with **MADE Scientific** as the named cell-and-gene-therapy sub-advisor, is pleased to submit this proposal for the activation of Abu Dhabi's HELM Cluster across Workstreams 2 and 3 of the 2026 Implementation Phase.

We have read and understood the Scope of Work in full and confirm:

- **Acceptance of all Terms and Conditions** specified in Section 12 of the SOW, including confidentiality, intellectual property assignment to DOH, conflict-of-interest disclosure, professional indemnity insurance, and governing law of the Emirate of Abu Dhabi.
- **Proposal validity** for a minimum of 90 days from the submission deadline.
- **Mobilization commitment** of a qualified team within 30 days of contract signing, in line with SOW Section 7.1.
- **Local presence** through EY's UAE practice with team members based in Abu Dhabi during implementation, supported by MADE Scientific's specialist CGT manufacturing leadership deployed from the United States.
- **Pricing** for the sub-advisory engagement is to be agreed between EY and MADE Scientific prior to contract execution; the consolidated commercial proposal will be submitted separately as required by SOW Section 11, Part 4.

The pages that follow are organised in line with **SOW Section 11, Proposal Requirements**.

Respectfully,

[Authorized EY Engagement Partner] Ernst & Young, MENA Healthcare & Life Sciences

[PLACEHOLDER, TO BE SIGNED PRIOR TO SUBMISSION]

Part 2: Understanding of Scope

This Part addresses **SOW Section 11, Part 2**, demonstrating EY × MADE Scientific's understanding of the project objectives, the strategic context behind the HELM Cluster Activation, and the specific requirements for the Cell & Gene Therapy and Strategic Partnerships workstreams.

Engagement Governance and Delivery Model

Effective delivery of the HELM Cluster CGT activation requires a governance architecture that preserves EY's role as prime contractor and single point of accountability to the Abu Dhabi Department of Health (DOH), while embedding MADE Scientific's deep ATMP technical expertise precisely where it is needed, in GMP facility design, regulatory framework development and international partnership origination. The structure below is designed to achieve this balance with full transparency, clear escalation paths and rigorous protection of confidential ATMP know-how.

Governance Structure

The engagement will operate under a three-tier governance model:

- **Tier 1, Executive Steering Committee (ESC).** Co-chaired by the EY Engagement Partner and a designated DOH senior executive, the ESC provides strategic direction, approves major deliverables and resolves any issues escalated beyond the project management layer. MADE Scientific's Chief Executive or Chief Operating Officer will attend as an invited technical advisor. The ESC convenes quarterly, aligned with the DOH's existing HELM Cluster governance cadence.
- **Tier 2, Joint Project Leadership.** Day-to-day delivery is led by an **EY Project Director** who owns the integrated work plan, client relationship and commercial management across all workstreams. A **MADE Scientific Technical Lead**, a senior CGT manufacturing and regulatory specialist, operates under the EY Project Director's coordination, leading the technical content for WS2.4.1 (CGT Strategy & Infrastructure) and WS2.4.2 (Strategic Partnerships). This dual-leadership model mirrors the Joint Steering Committee approach MADE Scientific deploys in its CDMO client engagements, where dedicated governance structures ensure executive oversight and cross-functional alignment.
- **Tier 3, Workstream Delivery Teams.** Specialist sub-teams are assembled for each deliverable, CGT Strategic Framework, ATMP Regulatory & Quality Framework, Partnership Agreements and Workforce Development Program, drawing on EY's consulting bench and MADE Scientific's subject-matter experts in GMP operations, quality assurance and multi-jurisdictional regulatory affairs (FDA/CBER, EMA, PMDA, DOH, MOHAP).

Reporting Cadence and DOH Touchpoints

FREQUENCY	FORUM	PARTICIPANTS	PURPOSE
Weekly	Project Status Call	EY Project Director, MADE Technical Lead, DOH Program Manager	Progress tracking, issue log review, near-term action items
Bi-weekly	Technical Deep-Dive	MADE Scientific SMEs, DOH technical counterparts, EY team	Detailed review of facility design, regulatory drafting, partnership pipeline
Monthly	Integrated Progress Report	Written submission to DOH	Consolidated status against milestones, risk register update, financial summary
Quarterly	Executive Steering Committee	ESC members as above	Strategic alignment, deliverable sign-off, course correction

All reporting artefacts will be prepared by EY, incorporating MADE Scientific technical inputs, ensuring a single consistent voice to the DOH.

Risk Management in a Novel Regulatory Environment

The UAE's ATMP regulatory landscape is still maturing, neither DOH nor MOHAP has yet promulgated a comprehensive, standalone ATMP framework equivalent to the EU's Regulation (EC) No. 1394/2007 or FDA's RMAT designation pathway [verification pending]. This creates both opportunity and risk. The engagement will manage regulatory uncertainty through:

- **Horizon scanning.** MADE Scientific will maintain a live regulatory tracker covering DOH, MOHAP, EMA, FDA/CBER and PMDA developments relevant to ATMPs, updated bi-weekly and shared with the EY project team. This draws on MADE Scientific's established regulatory compliance posture across FDA/CBER and EU Annex 1 frameworks.
- **Scenario-based framework design.** The ATMP Regulatory & Quality Framework deliverable will be structured to accommodate multiple regulatory evolution scenarios, ensuring the HELM Cluster's compliance architecture remains viable regardless of whether DOH adopts an EMA-aligned, FDA-aligned, or hybrid pathway.
- **Early regulator engagement.** The team will recommend and, where EY and DOH agree, facilitate, pre-submission dialogue with DOH and MOHAP to shape emerging ATMP guidelines proactively rather than reactively. Lessons from the EU experience, where developers lacking regulatory expertise found ATMP compliance "overwhelming" (Olesti et al., *Cytotherapy*, 2024), underscore the value of early and sustained regulator interaction.
- **Risk register with RAG status.** A dedicated risk register will track regulatory, technical, commercial and reputational risks, reviewed at every monthly reporting cycle and escalated per the pathway below.

Intellectual Property and Confidentiality Framework

ATMP manufacturing know-how, encompassing GMP process parameters, analytical methods, facility design specifications and quality system architectures, is among the most commercially sensitive intellectual property in the life sciences sector. The following principles will govern IP and confidentiality:

- **Background IP remains with originator.** MADE Scientific retains ownership of its pre-existing CDMO process knowledge, GMP facility design templates and proprietary quality frameworks. EY retains ownership of its consulting methodologies and analytical tools.
- **Foreground IP vests with DOH.** All deliverables produced under the engagement, the CGT Strategic Framework, Regulatory & Quality Framework, Partnership Agreements and Workforce Development Program, will be owned by the Abu Dhabi DOH as the commissioning authority, subject to final terms in the EY--DOH prime contract.
- **Mutual NDA and information barriers.** A tripartite Non-Disclosure Agreement will be executed prior to engagement commencement, with information classification tiers (Confidential, Restricted, Internal) and need-to-know access controls.
- **CDMO conflict safeguards.** MADE Scientific will implement internal information barriers to ensure that commercially sensitive HELM Cluster data is ring-fenced from its US-based CDMO client operations, consistent with the confidentiality protocols it maintains across its existing client portfolio.

Escalation Pathway

Issues that cannot be resolved at the working level follow a defined escalation chain:

1. **Workstream Lead → EY Project Director**, resolution target: 3 business days.
2. **EY Project Director → EY Engagement Partner + MADE Scientific Technical Lead**, resolution target: 5 business days.
3. **EY Engagement Partner → Executive Steering Committee**, convened on an ad-hoc basis for matters affecting deliverable timelines, budget, or DOH strategic objectives.

4. **ESC → EY and MADE Scientific Executive Sponsors**, reserved for contractual disputes or force-majeure events requiring senior corporate intervention.

At every escalation tier, the EY Project Director retains responsibility for DOH communication, ensuring the client receives a unified, coordinated response.

Pricing: TBD, placeholder only. To be agreed between EY and MADE Scientific prior to contract execution.

WS2.4.2, Workplan and Deliverables

Scope and Objective

Workstream 2.4.2 (Strategic Partnerships) is the execution arm of the HELM Cluster's CGT ambition. Where WS2.4.1 establishes the strategic architecture, WS2.4.2 converts that architecture into binding partnerships, a trained workforce and a regulatory-quality scaffold that positions Abu Dhabi as a credible ATMP jurisdiction from day one. MADE Scientific, operating as EY's named CGT sub-advisor, brings direct execution experience across every deliverable in this workstream, from its sovereign Gulf health authority advisory engagement in Saudi Arabia to its Made Foundry workforce program, which has graduated 275+ cell therapy professionals to date.

The deliverables below are sequenced to respect natural dependencies: partner identification and due diligence must precede term sheets; the regulatory & quality framework must be established before partnership agreements can reference compliance obligations; and workforce curriculum design must align with the modalities and manufacturing platforms selected in WS2.4.1.

Deliverable Summary Table

#	DELIVERABLE	OWNER (LEAD / SUPPORT)	TIMELINE	FORMAT	SUCCESS METRIC
D-1	**Partner Due Diligence Reports** (≥5 candidates evaluated, ≥3 shortlisted)	MADE Scientific (lead) / EY Strategy (review)	Weeks 1–10 (Oct-Dec 2026)	Structured PDF report per candidate; executive summary deck	≥5 candidates scored against weighted criteria matrix; ≥3 advance to term-sheet stage with DOH concurrence
D-2	**ATMP Regulatory & Quality Framework Document**	MADE Scientific (lead) / EY Regulatory & DOH (co-review)	Weeks 4–18 (Nov 2026-Feb 2027)	Master framework document (Word/PDF, ≥60 pp.) with annexes; companion policy brief for DOH leadership	Framework accepted by DOH and validated against ≥3 international benchmarks (EMA, FDA/CBER, PMDA); zero critical gaps at peer review
D-3	**Partnership Agreement Term Sheets** (≥2 formal agreements)	EY (lead, commercial negotiation) / MADE Scientific (technical annex & scope)	Weeks 12–30 (Jan-Jun 2027)	Executed term sheets with technical schedules; board-ready summary memoranda	≥2 term sheets signed by counterparties and DOH; each includes technology transfer, IP and quality obligations
D-4	**Workforce Development Program Curriculum**	MADE Scientific (lead, curriculum design) / EY (stakeholder alignment, local institution mapping)	Weeks 8–36 (Dec 2026-Jul 2027)	Curriculum framework document; module syllabi; competency assessment rubrics; train-the-trainer guide	Curriculum covers ≥4 pillars; endorsed by ≥1 UAE academic institution; first cohort enrolled by Sep 2027

D-1: Partner Due Diligence Reports

Purpose. Identify, evaluate and shortlist international CGT partners, including CDMOs, academic medical centres and technology licensors, whose capabilities complement the HELM Cluster's target modality portfolio (CAR-T, MSC, NK, iPSC, exosomes) and whose strategic intent aligns with Abu Dhabi's long-term sovereignty objectives.

Approach. MADE Scientific will apply a structured due diligence methodology informed by its own multi-modality CDMO operations across CAR-T, NK, TIL, MSC, HSC, iPSC and exosome platforms. Each candidate will be assessed across six dimensions:

- **Technical capability**, GMP manufacturing readiness, modality breadth, process development maturity
- **Regulatory standing**, licensure status with FDA/CBER, EMA, PMDA and/or relevant Gulf authorities (DOH, MOHAP, SFDA)
- **Strategic alignment**, willingness to co-invest, technology-transfer orientation, IP sharing posture
- **Financial viability**, balance sheet strength, funding trajectory, parent-company backing
- **Regional experience**, prior Gulf/MENA engagements, cultural fluency, logistics infrastructure
- **Workforce contribution**, ability to support training, secondment, or knowledge-transfer programs

Key Activities.

PHASE	WEEKS	ACTIVITY	OUTPUT
Landscape scan	1–4	Map ≥15 global CGT organisations across CDMO, academic and pharma segments	Long-list matrix with preliminary scoring
Desk-based diligence	4–8	Deep-dive on ≥8 candidates: public filings, regulatory databases, facility audits (where available), reference checks	Individual diligence dossiers (confidential)
Management engagement	6–10	Structured interviews / site visits with ≥5 shortlisted candidates	Interview summaries; site visit reports
Shortlist & recommendation	9–10	Weighted scoring, DOH alignment workshop, final shortlist of ≥3	Executive summary deck; recommendation memo to EY and DOH

MADE Scientific Differentiator. As an operating CDMO with 60,000 sq ft of GMP capacity at its Princeton headquarters and active relationships across the global cell therapy ecosystem, MADE Scientific evaluates potential partners not as external consultants but as manufacturing peers, capable of assessing cleanroom design, process robustness and quality system maturity from first-hand operational experience. Its prior advisory work with a sovereign Gulf health authority in Saudi Arabia, encompassing CAR-T and MSC manufacturing strategy for a multi-suite facility, provides directly transferable regional diligence expertise.

D-2: ATMP Regulatory & Quality Framework Document

Purpose. Develop a comprehensive regulatory and quality framework tailored to Abu Dhabi's emerging ATMP ecosystem, ensuring that the HELM Cluster's CGT operations are designed for multi-jurisdictional compliance from inception rather than retrofitted after the fact.

Scope. The framework will address the full ATMP lifecycle, from investigational product classification through GMP manufacturing, clinical trial authorisation, marketing authorisation and post-market pharmacovigilance, across the following regulatory domains:

- **Abu Dhabi DOH**, emirate-level healthcare regulation and facility licensing
- **UAE MOHAP**, federal pharmaceutical and biological product oversight
- **EMA**, EU ATMP classification (Regulation 1394/2007), GMP (EU Annex 1) and marketing authorisation via CAT/CHMP
- **US FDA/CBER**, BLA pathway, 21 CFR 1271 tissue establishment requirements, IND framework
- **Japan PMDA**, conditional and time-limited approval pathway for regenerative medicine products (SAKIGAKE designation)
- **Saudi SFDA**, cross-border alignment for Gulf CGT corridor opportunities

Structure of the Framework Document.

1. **Regulatory landscape analysis**, comparative matrix of ATMP/CGT classification, approval pathways and timelines across DOH, MOHAP, EMA, FDA, PMDA and SFDA
2. **GMP compliance architecture**, facility design requirements mapped to EU Annex 1 (2023 revision), PIC/S GMP Guide Annex 2A and FDA 21 CFR 211/600 series; MADE Scientific's Princeton facility is designed to US FDA and EU Annex 1 standards, providing a direct reference architecture
3. **Quality Management System (QMS) blueprint**, document hierarchy, deviation/CAPA management, change control, supplier qualification and batch release protocols
4. **Clinical trial authorisation pathway**, recommended DOH/MOHAP pathway for investigational ATMPs, benchmarked against EMA IMPD and FDA IND requirements
5. **Pharmacovigilance and post-market surveillance**, risk management plan template, periodic safety update reporting and registry design for long-term follow-up (≥15 years for gene therapy products per EMA guidelines)
6. **Gap analysis and roadmap**, identification of regulatory gaps in the current UAE framework with prioritised recommendations for DOH policy development

Success Criteria.

- Framework validated against ≥3 international regulatory benchmarks
- Zero critical gaps identified during independent peer review (conducted by EY regulatory practice)
- DOH formal acceptance of the framework as a reference document for HELM Cluster ATMP operations
- Companion policy brief delivered to DOH leadership within 2 weeks of framework finalisation

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D-3: Partnership Agreement Term Sheets (≥2)

Purpose. Convert the shortlisted partner candidates from D-1 into formal, binding (or binding-in-principle) partnership agreements that establish the commercial, technical and governance architecture for international CGT collaboration within the HELM Cluster.

Approach. EY will lead commercial negotiation and legal structuring, with MADE Scientific providing the technical annexes that define manufacturing scope, technology transfer protocols, quality obligations and workforce commitments. This division of labour ensures that term sheets are both commercially rigorous (EY) and technically credible.

Term Sheet Structure (indicative).

Each agreement is expected to address the following elements:

- **Partnership model**, JV, licensing, CDMO services agreement, or academic collaboration framework

- **Technology transfer scope**, modalities covered, process documentation requirements, analytical method transfer, reference standard provision
- **IP and data rights**, background IP ownership, foreground IP allocation, data access and publication rights
- **Quality and regulatory obligations**, mutual GMP audit rights, quality agreement, regulatory filing responsibilities, pharmacovigilance data sharing
- **Workforce provisions**, secondment commitments, training obligations, Emiratisation targets
- **Financial terms**, investment commitments, fee structures, milestone payments, revenue sharing (where applicable)
- **Governance**, joint steering committee composition, decision rights, dispute resolution, term and termination

Timeline and Milestones.

PHASE	WEEKS	ACTIVITY
Term sheet drafting	12–16	MADE Scientific prepares technical schedules; EY drafts commercial terms
Partner negotiation (Round 1)	16–22	Bilateral negotiations with ≥3 shortlisted partners
DOH alignment	20–24	Review of draft terms with DOH; incorporation of sovereign requirements
Final negotiation & execution	24–30	Closure of ≥2 term sheets; board-ready summary memoranda

Success Criteria.

- ≥2 term sheets fully executed by counterparties and endorsed by DOH by end of Week 30 (Jun 2027)
- Each term sheet includes explicit technology transfer, IP, quality and workforce provisions
- At least one agreement involves a Tier 1 international CGT organisation (top-20 global CDMO or top-50 academic medical centre by CGT clinical trial volume) [verification pending]

D-4: Workforce Development Program Curriculum

Purpose. Design a fit-for-purpose CGT workforce development curriculum that can be delivered within the HELM Cluster ecosystem, building Abu Dhabi's domestic talent pipeline from technician level through senior manufacturing scientist and reducing long-term dependence on expatriate specialists.

MADE Scientific's Proven Model. The curriculum design will be directly informed by MADE Scientific's **Made Foundry** program, which operates from its Princeton, NJ facility in partnership with leading regional academic institutions and has trained 275+ cell therapy professionals since inception. The program is structured around four curriculum pillars: Cell Therapy Fundamentals, GMP Operations, Quality Systems and Technical Skills. Made Foundry's institutional partnerships include a corporate workforce-development engagement (multi-million-dollar program value) and the leading regional universities curriculum co-development initiative ($64.5K).

Proposed Curriculum Architecture for HELM.

PILLAR	TARGET AUDIENCE	CORE MODULES	DELIVERY MODE
1. Cell Therapy Fundamentals	New entrants, BSc graduates, career-switchers	Cell biology for manufacturing; immunology of CAR-T/NK/TIL; stem cell biology (MSC, iPSC, HSC); vector biology for gene therapy	Classroom + e-learning; 80 hrs
2. GMP Manufacturing Operations	Manufacturing technicians, production supervisors	Cleanroom behaviour and gowning; aseptic technique; equipment operation (CliniMACS Prodigy, BioFlo bioreactors, fill-finish); batch record execution; environmental monitoring	Hands-on lab + simulation; 120 hrs
3. Quality Systems & Regulatory	QA/QC analysts, regulatory affairs staff	QMS fundamentals; deviation/CAPA management; batch release; analytical methods (flow cytometry, potency assays, sterility); DOH/MOHAP regulatory requirements; EMA/FDA comparator	Classroom + case studies; 80 hrs
4. Advanced Technical Skills	Senior scientists, process development leads	Process development and optimisation; tech transfer methodology; scale-up/scale-out strategies; cryopreservation and cold chain; data integrity and electronic batch records	Workshop + project-based; 100 hrs

Localisation and Emiratisation.

- Curriculum will be co-developed with ≥1 UAE academic institution (e.g., Khalifa University, MBZUAI, or UAE University) to ensure local accreditation pathways [verification pending]
- Arabic-language supplementary materials for Pillars 1 and 3
- Emiratisation-aligned intake targets to be agreed with DOH during stakeholder alignment phase
- Train-the-trainer program to build local instructional capacity within 18 months of first cohort

Key Activities.

PHASE	WEEKS	ACTIVITY	OUTPUT
Needs assessment	8–12	Stakeholder interviews (DOH, HELM tenants, UAE universities); gap analysis against Made Foundry baseline	Training needs assessment report
Curriculum design	12–20	Module development; competency framework; assessment rubric design	Draft curriculum document; module syllabi
Institutional alignment	18–28	Engagement with UAE academic partners; accreditation pathway mapping	MOU or LOI with ≥1 academic institution
Pilot delivery	28–36	First cohort (≥20 trainees); iterative refinement	Pilot completion report; trainee competency scores

Success Criteria.

- Curriculum endorsed by DOH and ≥1 UAE academic institution
- ≥4 curriculum pillars fully developed with module syllabi, assessment rubrics and instructor guides
- First cohort of ≥20 trainees enrolled by September 2027
- ≥80% of pilot cohort achieving "competent" or above on post-module assessments
- Train-the-trainer guide delivered, enabling local-led delivery within 18 months

Interdependencies and Sequencing

The four deliverables are deliberately sequenced to manage risk and maximise coherence:

- **D-1 (Due Diligence) feeds D-3 (Term Sheets):** Partner shortlisting must be complete before meaningful commercial negotiation can begin. The 2-week overlap (Weeks 9–10) allows early engagement with frontrunner candidates while final scoring is completed.
- **D-2 (Regulatory Framework) informs D-3 and D-4:** The quality and regulatory obligations embedded in partnership term sheets (D-3) must reference the framework established in D-2. Similarly, the Quality Systems & Regulatory pillar of the workforce curriculum (D-4) must align with the framework's QMS blueprint.
- **D-4 (Workforce Curriculum) is shaped by D-1 and D-3:** The modalities and manufacturing platforms brought in by international partners will influence the technical skills modules. Curriculum design begins in parallel but incorporates partner-specific content as term sheets crystallise.

Governance and Reporting

All deliverables will be managed under EY's engagement governance structure, with MADE Scientific reporting to the EY Workstream 2 Lead. Fortnightly progress reports will be provided to the EY engagement manager, with monthly steering committee updates to DOH. Deliverable acceptance will follow a two-stage gate: (1) EY quality review and (2) DOH formal sign-off.

Pricing

TBD, placeholder only. To be agreed between EY and MADE Scientific prior to contract execution.

WS2.4.1, CGT Strategy & Infrastructure: Our Approach

The establishment of a world-class cell and gene therapy (CGT) capability within the HELM Cluster represents a generational opportunity for Abu Dhabi, one that demands a strategy calibrated to the emirate's unique position at the intersection of sovereign ambition, regional disease burden and global manufacturing capacity constraints. Under EY's program leadership, MADE Scientific will serve as the specialist CGT sub-advisor responsible for translating strategic intent into an operationally credible infrastructure plan spanning facility design, operational model selection, technology transfer architecture, regulatory framework development and a phased scale-up roadmap from first-in-human clinical manufacturing through commercial supply.

Operational Model Options: Selecting the Right Architecture

The global ATMP CDMO market is projected to grow at a CAGR of 18.8% through 2032, driven by expanding clinical pipelines in oncology and rare diseases and the fact that many small and mid-sized biotech firms lack in-house GMP infrastructure (Credence Research, ATMP CDMO Market Size Report, 2025). This structural supply deficit creates a strategic opening for Abu Dhabi. Our approach will evaluate three operational archetypes and recommend a hybrid model optimised for the HELM context:

- **Fully Indigenous Model.** Abu Dhabi builds and operates a sovereign CGT manufacturing facility end-to-end. This model maximises long-term IP retention and workforce development but carries the highest capital risk and the longest time-to-first-product. It requires deep bench strength in process development, quality assurance and regulatory affairs, capabilities that take years to cultivate organically.

- **Hybrid CDMO Partnership Model (Recommended).** The HELM facility is established as a purpose-built GMP site operated under a joint-venture or managed-services agreement with an experienced international CDMO partner. This model mirrors the approach taken by emerging biotech hubs globally, where governments provide incentives to attract ATMP facilities and regional GMP sites support faster patient access through joint ventures that create shared investment models (Credence Research, ATMP CDMO Market Size Report, 2025). Technology transfer programs strengthen local expertise while the international partner de-risks early operations. MADE Scientific's direct CDMO operating experience, including its GMP manufacturing platform and prior Gulf advisory Gulf sovereign-ATMP advisory engagement in Saudi Arabia, positions the EY--MADE team to design and negotiate these structures with credibility.
- **Licensing / Platform-Access Model.** Abu Dhabi licenses validated manufacturing processes and platform technologies from established CGT developers, reducing process development timelines. This is best suited as a complementary strategy, for example, licensing a closed, automated CAR-T manufacturing platform to accelerate initial throughput while indigenous capabilities mature.

Our deliverable will be a decision matrix scoring each model against criteria including time-to-GMP-readiness, capital efficiency, IP ownership trajectory, workforce absorption rate and alignment with DOH's broader HELM Cluster vision.

GMP Facility Design Principles for a HELM-Based CGT Suite

Facility design for advanced therapies is fundamentally different from conventional biologics. Drawing on global best practices, MADE Scientific will develop conceptual design specifications anchored in the following principles:

- **Closed-system, automated manufacturing.** The global industry is converging on closed manufacturing platforms that reduce contamination risk, decrease manual variability and improve reproducibility across patient-specific batches (Credence Research, ATMP CDMO Market Size Report, 2025). Automation can reduce labour requirements by up to 60–70% and cut cost of goods by up to 50%, while enabling throughput of approximately 1,000 products per year in as little as 1,000 square feet of cleanroom space (Charles River / Ori Biotech, 2025). The HELM facility should be designed from inception around these next-generation platforms rather than retrofitting legacy open-process workflows.
- **Modular, multi-product flexibility.** The facility must accommodate both autologous (patient-specific) and allogeneic (off-the-shelf) manufacturing workflows. Modular GMP suites, with segregated Grade B/C cleanroom environments and Grade A isolator workstations, allow parallel processing of multiple therapy programs without cross-contamination risk. Investment in modular GMP facilities provides flexible capacity for multi-product pipelines (Credence Research, ATMP CDMO Market Size Report, 2025).
- **Integrated quality control.** Dedicated in-house QC laboratories co-located with manufacturing suites eliminate delays tied to third-party testing and accelerate release timelines, particularly for rate-limiting safety assays (OmniaBio, 2024). The HELM design should incorporate approximately 6,000–8,000 sq ft of dedicated QC space with capabilities for potency, sterility, identity and viral clearance testing.
- **Digital infrastructure.** Cloud-native manufacturing execution systems (MES), electronic batch records and real-time process analytics should be embedded from day one. Digital twins and AI-driven process optimisation are emerging as competitive differentiators among leading CDMOs and will support both regulatory compliance and data integrity at scale.

Global Partnership Strategy for Technology Transfer

No CGT hub has been built in isolation. The UK's Cell and Gene Therapy Catapult model demonstrates how public-private collaboration, combining government-funded GMP infrastructure with industry partnerships and structured apprenticeship programs, can catalyse an entire national ecosystem (CGT Catapult, UK Cell and Gene Therapy Skills Demand Report, 2019). Similarly, CTMC in Houston operates a patient-adjacent model co-located with MD Anderson Cancer Center, employing risk-sharing agreements with early-stage biotechs and academic collaborators and providing multi-year support until partners achieve commercial manufacturing readiness (CTMC, 2025).

MADE Scientific, as EY's named technical partner, will lead the identification and evaluation of potential technology transfer partners across three tiers:

- **Tier 1, Platform Technology Partners.** Global leaders in viral vector production (AAV, lentiviral), closed-system cell processing and gene editing platforms whose validated processes can be transferred to the HELM facility under licensing or co-development agreements.
- **Tier 2, CDMO Operating Partners.** Established ATMP CDMOs with multi-jurisdictional GMP certifications (FDA, EMA, PMDA, TGA) who can provide operational management during the facility's ramp-up phase and train the local workforce to independence. Key players in this space include Lonza, Thermo Fisher Scientific, FUJIFILM Diosynth Biotechnologies and AGC Biologics (Credence Research, ATMP CDMO Market Size Report, 2025).
- **Tier 3, Academic and Clinical Research Partners.** Regional and international institutions that can serve as sources of clinical-stage ATMP candidates for manufacturing at the HELM facility, ensuring a pipeline of products to sustain utilisation rates.

Each partnership will be structured to include explicit knowledge-transfer milestones, Emiratisation targets for technical roles and IP co-ownership provisions where appropriate.

Regulatory Framework Design Aligned to DOH and ICH/EMA Standards

Abu Dhabi's regulatory environment for ATMPs is nascent, presenting both a challenge and an opportunity to design a framework that is globally harmonised from inception rather than retroactively patched. Working under EY's regulatory workstream leadership, MADE Scientific will develop an ATMP Regulatory and Quality Framework that:

- **Aligns with ICH Q-series guidelines** (Q5A, Q5D, Q8--Q12) and EMA's ATMP-specific regulatory pathway (Regulation EC No. 1394/2007), ensuring that products manufactured in Abu Dhabi are positioned for mutual recognition or accelerated review in major markets.
- **Incorporates multi-jurisdictional GMP standards.** The framework will reference FDA 21 CFR Parts 210/211 and 1271, EMA Annex 1 (2023 revision), PMDA standards for regenerative medicine products and DOH/MOHAP local requirements, enabling the HELM facility to pursue multi-authority GMP certification analogous to the model employed by leading global CDMOs such as Minaris, which holds concurrent FDA, EMA, TGA, PMDA and MFDS GMP certificates.
- **Establishes a DOH ATMP Classification and Approval Pathway**, a dedicated regulatory track for advanced therapies distinct from conventional biologics, with provisions for hospital exemptions, compassionate use and conditional approvals that reflect the unique risk-benefit profile of CGTs.
- **Embeds pharmacovigilance and post-market surveillance** requirements appropriate for therapies with long-term follow-up obligations (typically 15 years for gene therapies involving integrating vectors).

Phased Infrastructure Roadmap: Clinical to Commercial Scale

We propose a three-phase roadmap calibrated to the SOW delivery timeline (completion by July–September 2026 for framework and design deliverables) while establishing the trajectory for physical build-out beyond the engagement period:

Phase 1, Foundation (Months 1–6, within SOW period). Finalise the CGT Strategic Framework, complete operational model selection, issue GMP facility conceptual design specifications and execute ≥2 partnership term sheets. Deliver the ATMP Regulatory and Quality Framework to DOH for consultation. Initiate workforce needs assessment.

Phase 2, Build-Out (Months 7–24, post-SOW). Detailed engineering design and construction of the HELM CGT suite. Procurement of closed-system manufacturing platforms and QC instrumentation. Recruitment and training of initial GMP operations team (target: 40–60 FTEs). Submission of GMP licence application to DOH/MOHAP. Execution of first technology transfer agreement with a Tier 1 or Tier 2 partner.

Phase 3, Activation and Scale (Months 24–48, post-SOW). GMP commissioning, process validation and first clinical-grade manufacturing campaign. Expansion from clinical-scale (single-suite, ≤200 patient batches/year) to commercial-scale (multi-suite, ≥1,000 doses/year) as the product pipeline matures. Pursuit of international GMP certifications (EMA, FDA) to position the HELM facility as a regional CDMO hub serving the broader MENA market.

This phased approach balances Abu Dhabi's ambition for speed with the operational reality that CGT manufacturing excellence is built through disciplined capability accumulation and that the EY--MADE Scientific team brings both the strategic vision and the hands-on manufacturing expertise to guide that journey from blueprint to first patient dose.

WS2.4.2, ATMP Regulatory & Quality Framework

Rationale

The establishment of a CGT manufacturing capability within the HELM Cluster requires a purpose-built regulatory and quality architecture that satisfies Abu Dhabi's unique dual-authority governance structure while achieving international GMP equivalence from inception. MADE Scientific, as EY's named CGT sub-advisor, brings direct experience designing multi-jurisdictional compliance frameworks for ATMP facilities in the Gulf region, including the sovereign Gulf ATMP facility in Saudi Arabia, where a triple-jurisdiction strategy (SFDA, FDA, EMA) was anchored in EU GMP Annex 1 (2023) with ICH Q8/Q9/Q10/Q12 quality system integration. This section sets out the proposed regulatory and quality framework for the HELM CGT facility, structured for DOH endorsement and international recognition.

UAE Regulatory Jurisdiction: Federal (MOHAP) vs. Emirate-Level (DOH)

The UAE operates a dual-tier healthcare regulatory system. At the federal level, the Ministry of Health and Prevention (MOHAP) sets national pharmaceutical policy, maintains the national drug registry and regulates pharmaceutical manufacturing and distribution across most emirates. However, Abu Dhabi exercises autonomous health regulatory authority through the Department of Health, Abu Dhabi (DOH), which licenses healthcare facilities, regulates clinical practice and oversees pharmaceutical activities within the emirate under its own legislative framework (DOH, Healthcare Facility Regulation, 2019) [verification pending].

For ATMPs specifically, the jurisdictional landscape is still maturing. Neither MOHAP nor DOH has published a standalone ATMP-specific regulation analogous to the EU's Regulation (EC) 1394/2007. Current practice classifies cell and gene therapy products under broader biologics or pharmaceutical frameworks, creating an opportunity and a necessity, for the HELM engagement to propose a fit-for-purpose ATMP regulatory pathway to DOH. MADE Scientific recommends that the HELM CGT facility seek primary manufacturing authorization from DOH (as the Abu Dhabi licensing authority) while aligning its dossier structure and quality standards to internationally recognized frameworks, thereby facilitating future mutual recognition or reliance pathways with MOHAP and export-market regulators.

Proposed GMP Framework: EU ATMP Regulation and ICH Q10 Alignment

The recommended compliance architecture is anchored in the EU regulatory model, the most mature and comprehensive ATMP-specific framework globally, supplemented by ICH harmonized guidelines:

- **EU Regulation (EC) 1394/2007**, the foundational ATMP regulation establishing classification criteria, centralized marketing authorization and post-authorization traceability requirements including 30-year follow-up obligations (European Parliament and Council, Regulation (EC) 1394/2007, 2007).
- **EudraLex Volume 4, Annex 2A (2017)**, GMP guidelines specific to ATMPs, addressing risk-based approaches to facility design, aseptic processing and in-process controls for biological starting materials (European Commission, EudraLex Vol. 4 Annex 2A, 2017).
- **EU GMP Annex 1 (2023)**, the revised contamination control strategy (CCS) requirements mandating a holistic, lifecycle approach to sterility assurance, directly applicable to cleanroom design and environmental monitoring programs (European Commission, EU GMP Annex 1, 2023).

- **ICH Q10, Pharmaceutical Quality System**, providing the overarching quality management framework encompassing management responsibility, continual improvement and knowledge management across the product lifecycle (ICH, Q10 Guideline, 2008).
- **ICH Q9(R1), Quality Risk Management**, the 2023 revision strengthening requirements for formality and documentation of risk assessments, critical for ATMP process characterization (ICH, Q9(R1), 2023).

This approach mirrors the harmonized design strategy MADE Scientific deploys for sovereign ATMP facilities operating across multiple regulatory jurisdictions: a unified design baseline anchored in EU GMP Annex 1 (2023) and ICH Q8/Q9/Q10/Q12 quality systems, with long-horizon traceability aligned to ATMP Regulation (EC) 1394/2007. Such a multi-jurisdiction design baseline simplifies dual review by EMA, FDA, and host-country regulators, and is well-suited to a DOH framework intended to attract both regional patients and international CDMO clients.

Quality System Elements for a New CGT Manufacturer

A greenfield ATMP manufacturing facility within the HELM Cluster must establish the following quality system elements prior to first GMP batch release:

QUALITY SYSTEM ELEMENT	GOVERNING STANDARD	PURPOSE
Pharmaceutical Quality System (PQS)	ICH Q10	Overarching QMS governance, management review, CAPA
Contamination Control Strategy (CCS)	EU GMP Annex 1 (2023)	Lifecycle-based sterility assurance for aseptic manufacturing
Validation Master Plan (VMP)	ICH Q8/EU GMP Annex 15	IQ/OQ/PQ protocols for equipment, utilities and processes
Electronic QMS (eQMS)	21 CFR Part 11 / EU GMP Annex 11	Document control, deviation management, electronic records
Change Control & CAPA	ICH Q10 / PIC/S PE 009	Systematic management of deviations, changes and corrective actions
Batch Record & Release System	EudraLex Vol. 4 Annex 2A	ATMP-specific batch documentation and Qualified Person release
Supplier Qualification Program	ICH Q10 / EU GMP Ch. 5	Qualification of critical raw materials (vectors, cytokines, media)
Traceability & Biovigilance	Regulation (EC) 1394/2007	30-year donor-to-patient traceability for all ATMP products
Training & Competency Framework	PIC/S GMP Guide	Role-based qualification for aseptic technique, biosafety and ATMP handling

Pathway to DOH Manufacturing Authorization

MADE Scientific proposes a phased authorization pathway structured around five milestones:

1. **Pre-submission engagement**, Formal meeting with DOH to present the ATMP manufacturing concept, proposed regulatory dossier structure and request for designation of a lead assessor. This mirrors the structured pre-submission program recommended for SFDA engagement at a sovereign Gulf health authority.
2. **Facility design dossier**, Submission of the site master file, cleanroom classification rationale (EU GMP Grade B background / Grade A at point of work), CCS and environmental monitoring plan for DOH design-stage review.
3. **Quality system readiness**, Demonstration of an operational PQS, eQMS and VMP prior to commissioning, qualification and validation (CQV) activities.
4. **CQV execution and pre-approval inspection**, Completion of IQ/OQ/PQ with full documentation, followed by DOH facility inspection against agreed GMP standards.

5. **Manufacturing license issuance**, DOH authorization to manufacture ATMPs, with conditions for ongoing compliance monitoring, periodic re-inspection and annual product quality reviews.

Comparator Regulatory Frameworks: International Benchmarking

To inform the DOH framework design, MADE Scientific will benchmark against three comparator jurisdictions with established or emerging ATMP regulatory pathways:

- **EU / EMA**, The gold standard. Regulation (EC) 1394/2007 provides a dedicated ATMP classification and centralized authorization pathway via the Committee for Advanced Therapies (CAT). EudraLex Annex 2A offers ATMP-specific GMP guidance. The EMA's new clinical-stage ATMP guideline (effective July 2025) and pilot program for academic ATMP developers further strengthen the framework's relevance to the HELM model.
- **Saudi Arabia / SFDA**, The nearest regional comparator. SFDA regulates ATMPs under its Biological Products Guidelines and evolving ATMP-specific framework, with Casgevy (exa-cel) approved for clinical trial as a precedent. SFDA is a PIC/S member, ensuring GMP inspection alignment. the sovereign Gulf ATMP facility's experience navigating SFDA's developing ATMP landscape provides directly transferable lessons for DOH engagement.
- **Singapore / HSA**, The Health Sciences Authority regulates cell, tissue and gene therapy products under the Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021, enacted pursuant to the Health Products Act. HSA's framework is notable for its risk-proportionate approach, expedited pathways for products addressing unmet medical needs and alignment with PIC/S GMP standards, offering a pragmatic model for a jurisdiction building ATMP capability from a comparable starting position (HSA, Regulatory Overview for Cell, Tissue and Gene Therapy Products, 2021) [verification pending].

MADE Scientific's Role Under EY

Within this workstream, MADE Scientific will serve as EY's specialist sub-advisor responsible for drafting the ATMP Regulatory & Quality Framework document, conducting the international benchmarking analysis and facilitating DOH pre-submission engagement. All deliverables will be reviewed and issued under EY's quality assurance process and presented jointly to DOH leadership. MADE Scientific's prior experience designing the multi-jurisdictional compliance strategy for the sovereign Gulf ATMP facility, including management of risks related to "evolving ATMP regulatory frameworks" and "EU Annex 1 (2023) compliance gaps", provides a directly relevant precedent for this engagement.

Pricing: TBD, placeholder only. To be agreed between EY and MADE Scientific prior to contract execution.

The HELM Life Science Cluster: Abu Dhabi's CGT Platform

Abu Dhabi's HELM (Health, Education, Life sciences, Manufacturing) Cluster represents the Emirate's strategic vehicle for building an integrated advanced biomanufacturing ecosystem, one that unites clinical institutions, GMP production infrastructure, workforce training and regulatory enablement within a single coordinated framework. For cell and gene therapy, the HELM Cluster is not merely a real estate development; it is the institutional architecture through which Abu Dhabi intends to establish sovereign ATMP manufacturing capacity and position itself as the Gulf's CGT hub.

Governance and Institutional Anchors

The HELM Cluster operates under the strategic direction of the Abu Dhabi Department of Health (DOH), which serves as the Emirate's healthcare regulator and the principal authority overseeing life sciences industrialization policy [verification pending]. The DOH's role as both regulator and ecosystem architect gives the Cluster a structural advantage: regulatory pathway development and manufacturing infrastructure investment can advance in parallel rather than sequentially.

Abu Dhabi's health ecosystem provides a formidable institutional foundation. M42, the Abu Dhabi-based integrated health group, operates a network of hospitals and specialty centers that would serve as the clinical demand anchor for HELM-based CGT manufacturing [verification pending]. The Abu Dhabi Stem Cells Center (ADSCC), which hosted the Second Bone Marrow Transplant and Cellular Therapy Congress in October 2024, convening global experts in CAR-T therapy, TIL engineering and TCR innovations, demonstrates the Emirate's existing commitment to cellular therapy research and clinical translation (Suárez Formigo et al., Frontiers in Immunology, 2025). Cleveland Clinic Abu Dhabi has been identified at the planning stage for a CAR-T partnership model, further signaling institutional readiness. The UAE government has launched nationwide initiatives to promote access to innovative therapeutic strategies, reflecting "a comprehensive and forward-looking national approach to oncology, integrating prevention, early diagnosis and access to advanced therapies" (Suárez Formigo et al., 2025).

CGT Infrastructure Requirements

The HELM Cluster's CGT activation requires purpose-built infrastructure that goes well beyond conventional laboratory space. Drawing on the design principles validated by the sovereign Gulf health authority's ATMP manufacturing campus in the Gulf region, the MENA region's first such facility, the Abu Dhabi CGT platform will need to incorporate:

- **GMP production suites** classified to EU GMP Grade B/C standards (Grade A at point of work via biological safety cabinets), compliant with EU Annex 1 (2023) contamination control requirements
- **Modular cleanroom architecture** enabling phased deployment and capacity ramp-up aligned with demand, an approach that reduces upfront capital exposure and compresses commissioning timelines to 18–20 months
- **Dedicated QC laboratories** for in-process and release testing, with sample transfer pathways designed to prevent operational bottlenecks between production and analytical functions
- **Cryopreservation and cell banking infrastructure** supporting both autologous patient-specific products and allogeneic off-the-shelf inventory
- **Multi-regulatory compliance design** meeting DOH, MOHAP, EMA, FDA and SFDA requirements simultaneously, essential for a facility intended to serve both domestic patients and regional CDMO clients

The facility design must also accommodate multiple modalities, CAR-T, MSC, TIL, NK and iPSC-derived therapies, with strict segregation of manufacturing processes to prevent cross-contamination between different therapeutic products.

Regulatory Fast-Track and DOH Alignment

A critical enabler for the HELM Cluster's CGT pillar is the development of an ATMP-specific regulatory framework within the DOH and MOHAP architecture. Currently, no dedicated ATMP regulatory pathway exists in the UAE comparable to the EMA's Committee for Advanced Therapies (CAT) or the SFDA's emerging CGT-specific guidelines [verification pending]. The EY × MADE Scientific engagement under WS2.4.1 will deliver an ATMP Regulatory & Quality Framework designed to harmonize UAE requirements with international standards, creating the regulatory infrastructure that makes commercial-scale CGT manufacturing viable within the HELM Cluster.

The SFDA's trajectory in Saudi Arabia provides a useful precedent: the authority approved Casgevy as the first gene therapy for sickle cell disease and beta-thalassemia in the Kingdom in December 2024 and has increased CGT clinical trial approvals by 40% year-over-year. Abu Dhabi's DOH has the opportunity to leapfrog by designing its ATMP framework from the outset with international harmonization built in, rather than retrofitting existing pharmaceutical regulations.

Benchmarking Against Global CGT Cluster Models

The HELM Cluster's CGT ambition is not without precedent. Three international models offer instructive parallels and cautionary lessons:

Cell and Gene Therapy Catapult (United Kingdom). Established by Innovate UK as a not-for-profit centre of excellence, the CGT Catapult's core mission is "building a world-leading cell and gene therapy sector in the UK as a key part of a global industry" (CGT Catapult, ct.catapult.org.uk). Its Advanced Therapy Campus in Stevenage, north of London, has become a magnet for CGT companies, anchored by the Catapult's own GMP manufacturing centre and surrounded by a growing cluster of commercial manufacturers (The Global Stem Cell Economy, GSCN White Paper). The Catapult's annual UK GMP Manufacturing Survey tracks national capacity growth, reporting a 14% increase in total manufacturing space in 2022 alone, with product exports reaching the US, EU, Asia, Africa and Australasia (CGT Catapult, UK GMP Manufacturing Survey, 2022). The Catapult model demonstrates that a government-backed anchor institution with shared GMP infrastructure can catalyze an entire commercial ecosystem. Abu Dhabi's HELM Cluster should adopt this anchor-tenant logic.

ACTRIS (Singapore). The Advanced Cell Therapy and Research Institute, Singapore, was established in April 2020 as the national and regional centre of excellence for cellular therapeutics. ACTRIS's mandate spans the full value chain, "translational research and development, manufacturing, clinical service provision and commercialisation across the healthcare, academic and industrial sectors" and includes workforce training, regulatory facilitation and standardization of ancillary materials (ACTRIS, actris.sg; ISCT 2026 Partners Directory). Singapore's model is particularly relevant to Abu Dhabi: a small, wealthy, government-directed economy using a purpose-built national institution to leapfrog into advanced therapy manufacturing. ACTRIS demonstrates that a city-state can compete globally in CGT by integrating clinical demand, manufacturing capability and regulatory agility within a single coordinated program.

A sovereign Gulf health authority ATMP Manufacturing Campus. The most directly relevant comparator is the sovereign Gulf health authority's large-footprint ATMP manufacturing campus with a multi-suite modular cleanroom architecture, dedicated QC laboratory capacity and comprehensive support infrastructure. Backed by a sovereign mandate and a Day 1 investment of a substantial sovereign capital commitment, the facility is designed as a Hybrid Academic-CDMO model, serving both the sovereign Gulf health authority's internal clinical programs and external CDMO clients across the GCC. The consortium of an international modular cleanroom partner (modular cleanrooms), MADE Scientific (CQV and operations) and EY (PMO governance) provides the execution template that Abu Dhabi can adapt and accelerate.

The lesson from all three models is consistent: successful CGT clusters require a government-backed anchor institution, purpose-built GMP infrastructure, integrated regulatory pathways and deliberate workforce development. The HELM Cluster has the institutional architecture to deliver all four. What it requires now is the technical CGT expertise to translate that architecture into operational reality, precisely the capability that EY, with MADE Scientific as its named technical partner, bring to Workstream 2.

Part 3: Proposed Work/Project Plan

This Part addresses **SOW Section 11, Part 3**, detailed methodology, approach, work breakdown structure, and project schedule for **Workstream 2 (Cell & Gene Therapy Development)** and **Workstream 3 (Strategic Partnerships and Global Positioning)**.

Our Understanding

The HELM Cluster is the Department of Health, Abu Dhabi's flagship initiative to anchor advanced biomanufacturing in the Emirate. WS2 and WS3 require a strategic framework, a regulatory pathway, formal global partnerships, and a workforce-development model, all to be delivered in 2026 in alignment with the Future Health 2026 Showcase.	1. The HELM CGT activation is a multi-workstream program of strategic significance, which carries a high risk of scope or schedule slippage if not closely governed. 2. The cell-and-gene-therapy modality set adds technical and regulatory complexity beyond conventional biologics. 3. The program requires a rare combination of capital-projects governance experience and operational ATMP manufacturing expertise. 4. Multi-jurisdiction regulatory alignment (DOH, MOHAP, FDA, EMA, PMDA) must be designed in from Day 1. 5. This is Abu Dhabi's first sovereign-scale ATMP initiative, placing extra responsibility on the consortium to bring proven Gulf-ATMP delivery models.

Our Perspective on Advanced-Therapy Capital Programs

Drawing on EY's global capital-projects practice and MADE Scientific's hands-on ATMP technical leadership, the consortium organises advanced-therapy program delivery around **eight key questions** spanning the full lifecycle:

1. What pre-work secures strategic alignment with the sponsor and the host regulator before kick-off?	5. What governance, controls and decision rights must be in place at program initiation to set up for success?	8. How does Abu Dhabi maximise long-term value from the HELM CGT investment, through continuous capability upgrade, ecosystem expansion and global benchmarking?
2. What should be defined ahead of time to future-proof the program (modality breadth, throughput envelopes, capacity for expansion)?	6. What goes into a successful CGT facility design and regulatory pathway, drawing on global best practice and ATMP-specific standards (EU GMP Annex 1, ICH Q-series, 21 CFR 1271)?	
3. What are the characteristics of a high-quality ATMP technical partner, and what should DOH look for?	7. What are the common pitfalls during CGT program execution, and how does the consortium mitigate them through active program governance?	
4. Which partnership and contracting model is right for each workstream activity, direct delivery, licensed platform access, JV, or fee-for-service?		

The remainder of Part 3 demonstrates how the EY consortium addresses each of these questions across **Workstream 2 (CGT Strategy & Infrastructure; Strategic Partnerships & Regulatory Development)** and **Workstream 3 (Strategic Partnerships & Global Positioning; ADGHW 2026 Showcase)**.

Our Approach

The workstream structure follows the SOW exactly:

- **WS2.4.1, CGT Strategy & Infrastructure** (SOW §4.2.1)
- **WS2.4.2, Strategic Partnerships and Regulatory Development** (SOW §4.2.2)
- **WS3.4.3.1, Strategic Partnerships Development** (SOW §4.3.1)
- **WS3.4.3.2, ADGHW 2026 Showcase and Communication** (SOW §4.3.2)

Workstream 2, Cell & Gene Therapy Development

MADE Scientific: Gulf Region Track Record

Flagship Sovereign Gulf ATMP Engagement ATMP GMP Facility, Flagship Gulf Engagement

MADE Scientific's flagship Gulf advisory engagement is its ongoing role as the designated technical and GMP sub-advisor on a sovereign ATMP GMP manufacturing facility program for a leading Gulf-region sovereign health authority. This is a landmark initiative, the first purpose-built, dedicated cell and gene therapy manufacturing facility in the MENA region, with a substantial multi-year sovereign capital commitment and a long-horizon economic-impact thesis.

Scope. Under the EY-led PMO engagement, MADE Scientific serves as the specialist GMP and technical operations partner across the full multi-year project lifecycle. Specific responsibilities span five critical workstreams:

- **Business case and project delivery strategy:** Baseline scope assessment, long-term facility planning informed by industry trends and continuous improvement advisory.
- **Concept definition and design:** Ensuring facility design complies with GMP guidelines, SFDA regulations and international standards (EMA, FDA); verifying cleanroom standards and process equipment suitability for advanced therapies; and designing for scalability, flexibility and future expansion.
- **Procurement and contract management:** Screening, selecting and managing vendors and suppliers to meet quality and compliance standards; supporting contract negotiations in the sovereign Gulf health authority's interest with elements of Integrated Project Delivery.
- **Operational readiness and handover:** Overseeing commissioning and validation (IQ/OQ/PQ) to GMP standards; implementing lean interventions; ensuring smooth contractor-to-client handover with early onboarding of the operational team; and standing up an Integration Management Office for Day 1 launch.
- **Quality and regulatory compliance:** Serving as the technical verification authority on behalf of a sovereign Gulf health authority for GMP readiness across people, processes and production equipment, with CQV execution through a multi-year operations support period.

Team deployed. MADE Scientific has fielded senior leadership including its VP Quality & Compliance (25+ years in biologics and gene therapy), VP Development (15+ years in technology transfer and manufacturing), VP Technical Operations and Senior Director of Project Management alongside a broader support team with cross-functional expertise spanning cell therapy, gene therapy, nucleic acids and biologics.

Facility parameters. the sovereign Gulf ATMP facility encompasses a multi-thousand-square-metre footprint with a multi-suite, modular cleanroom architecture organised in clusters, ISO 14644-certified cleanrooms, QC laboratories and educational areas. The design achieves triple-jurisdiction regulatory compliance (SFDA, FDA, EMA) through a harmonized approach anchored in EU GMP Annex 1 (2023).

Other Gulf and MENA Advisory Work

Beyond a sovereign Gulf health authority, the knowledge base does not document additional completed Gulf or MENA advisory engagements by MADE Scientific [verification pending]. However, the firm's broader client portfolio, including GMP manufacturing partnerships with leading academic medical centers and biopharma sponsors across autologous and allogeneic modalities, demonstrates the operational model and regulatory fluency that underpin its Gulf advisory credibility.

Lessons and Relationships Transferable to Abu Dhabi

the sovereign Gulf ATMP engagement provides MADE Scientific with directly transferable capabilities for the Abu Dhabi HELM Cluster activation:

- **Gulf regulatory navigation.** Working within the SFDA framework while maintaining EMA and FDA harmonization has given the team practical experience in the multi-jurisdictional regulatory architecture that Abu Dhabi's DOH and MOHAP frameworks similarly require.
- **Modular GMP facility design.** the sovereign Gulf ATMP facility's modular cleanroom approach, using bio-containment boxes and clustered configurations from a leading international modular cleanroom EPC partner, offers a proven design template adaptable to HELM Cluster infrastructure planning.
- **Workforce development.** MADE Scientific has delivered multi-segment training programs covering cell processing, aseptic practices, flow cytometry and cell therapy best practices, directly supporting capability building for Gulf-based operators. This experience maps directly to WS2.4.2 workforce development requirements.
- **EY--MADE Scientific operating rhythm.** the sovereign Gulf ATMP project has established a tested governance model, with EY leading PMO oversight and MADE Scientific providing GMP technical authority, that can be replicated seamlessly for the HELM engagement, eliminating the integration risk inherent in assembling a new advisory team.
- **Existing Gulf relationships.** The senior MADE Scientific personnel deployed on a sovereign Gulf health authority maintain active relationships with SFDA regulators, GCC healthcare leaders and international EPC contractors operating in the region, providing a warm network for Abu Dhabi partnership development [verification pending].

Commercial Terms

Commercial terms for the EY × MADE Scientific UAE HELM CGT sub-advisory engagement are to be agreed between EY and MADE Scientific prior to contract execution. All fees, milestones and payment schedules referenced herein are indicative placeholders only and do not constitute a binding offer.

Why EY + MADE Scientific

The HELM Cluster CGT Development workstream demands a rare combination of capabilities: world-class management consulting at the sovereign-government level *and* hands-on operational expertise in GMP cell and gene therapy manufacturing. Neither discipline alone is sufficient. A strategy consultancy without manufacturing depth will produce frameworks that cannot withstand the realities of cleanroom operations, regulatory inspection, or process scale-up. A CDMO without government advisory infrastructure will lack the stakeholder management, program governance and institutional credibility required to move a national health authority from vision to execution. The EY--MADE Scientific partnership eliminates this gap entirely.

EY: Regional Authority and Consulting Infrastructure

EY brings an unmatched platform for sovereign health sector engagements in the Gulf. The firm maintains deep, long-standing relationships with government entities across the GCC, including healthcare authorities, economic development agencies and royal-court-level decision-makers. EY practitioners have led complex engagements spanning strategy development, supply chain management, national policy development, market entry strategies and pharmaceutical facility business cases across the MENA region, Europe and the United States, working with leading regional and international life sciences organisations. EY's capital projects consulting team operates across India, Europe, the Middle East and Africa, providing program governance, schedule and budget control, stakeholder coordination and risk escalation at scale.

Critically, EY has already been competitively evaluated and selected as the highest-scoring bidder for the sovereign Gulf health authority cGMP ATMP Facility PMO engagement in Saudi Arabia, achieving the highest technical score (55%) and overall evaluation result (80%) against international competitors including KPMG and Takamol. This precedent demonstrates that EY's life sciences consulting methodology has been validated by a leading Gulf healthcare institution in a directly analogous CGT infrastructure program.

MADE Scientific: Manufacturing Operations Expertise

MADE Scientific is a US-based ATMP CDMO headquartered in Princeton, New Jersey, operating within the established New Jersey Cell Therapy Corridor. The firm offers comprehensive expertise across both autologous and allogeneic cell-based therapies, spanning CAR-T, TCR and Treg therapies; NK and CAR-NK cells; tumour-infiltrating lymphocytes (TILs); mesenchymal stem cells (MSCs); hematopoietic stem cells (HSCs); induced pluripotent stem cells (iPSCs); dendritic cells; extracellular vesicles; and cell encapsulation technologies. This breadth of modality coverage is directly relevant to the HELM Cluster's ambition to establish a multi-modality CGT manufacturing hub.

MADE Scientific maintains BSL-2-compliant GMP infrastructure with viral transduction capabilities across lentiviral, retroviral and adeno-associated viral vector systems, as well as non-viral gene transfer technologies including electroporation and microfluidic delivery platforms. The firm's facility has received sustained recent capital investment from its parent company, GC Corporation, ensuring financial stability and continued infrastructure expansion. Its integrated service model spans process and analytical development, technology transfer, clinical-to-commercial GMP manufacturing, quality control, regulatory submission support and stability studies, precisely the end-to-end capability set required to advise Abu Dhabi on building a sovereign CGT manufacturing operation from the ground up.

Proven Partnership: The Sovereign Gulf Health Authority Precedent

The EY--MADE Scientific consortium is not a theoretical pairing. The two organisations are currently operating as an integrated team on the sovereign Gulf health authority ATMP cGMP Facility Program in the Gulf region, a multi-million-USD advisory engagement delivering for a landmark ATMP manufacturing campus. Within this EY-led consortium, EY leads program governance, schedule oversight and stakeholder management, while MADE Scientific serves as the CQV and Operations Partner responsible for GMP readiness across people, processes and production equipment; commissioning, qualification and validation execution; training and SOP delivery; and technical verification authority on behalf of a sovereign Gulf health authority. MADE Scientific's leadership, including its CEO, VP Quality & Compliance (25+ years in biologics and gene therapy) and VP Development (15+ years in process development and technology transfer), are embedded in the program's Subject Matter Expert Panel alongside EY's senior life sciences principals.

This active Gulf engagement means the consortium arrives at the HELM Cluster with battle-tested operating rhythms, a shared governance model and first-hand knowledge of the regulatory, cultural and institutional dynamics of building CGT infrastructure in the GCC. No competing team can credibly offer this combination of strategic consulting scale and operational manufacturing authority, already proven in a directly comparable sovereign ATMP program.

WS2.4.1, Phased Timeline

Approach to Phasing

The seven-month engagement is structured into four sequential phases, each gated by a formal milestone review with EY and DOH leadership. This phasing ensures that strategic recommendations are grounded in rigorous discovery before commitments are made, that regulatory and infrastructure frameworks are stress-tested against global benchmarks (EMA, FDA, PMDA, DOH/MOHAP) and that all deliverables achieve handoff-ready maturity by the contractual close in September 2026.

MADE Scientific, as CGT sub-advisor to EY, will lead the technical and scientific workstreams within each phase while EY retains overall program governance, client relationship management and integration with parallel HELM Cluster workstreams.

Phase Table, WS2.4.1 CGT Strategy & Infrastructure

Phase 1, Discovery & Assessment	M1--M2 (Jan–Feb 2026)	• Conduct on-site landscape assessment of existing Abu Dhabi CGT assets, clinical capabilities and infrastructure readiness across HELM Cluster anchor institutions • Map current DOH and MOHAP regulatory posture for ATMPs, including gap analysis against EMA (EC No 1394/2007), FDA (21 CFR 1271) and PMDA frameworks • Benchmark Abu Dhabi against comparator CGT hubs to identify competitive positioning levers • Catalogue regional disease burden and unmet need relevant to CGT modalities (e.g., haemoglobinopathies, inherited metabolic disorders prevalent in MENA populations) • Stakeholder interviews with DOH, SEHA/PureHealth, Khalifa University and prospective industry tenants • Deliver preliminary findings briefing to EY engagement leadership	**GATE 1, "Landscape Baseline Approved"** EY + DOH sign-off on Discovery Report comprising: current-state assessment, regulatory gap matrix, competitive benchmark scorecard and prioritised opportunity longlist
Phase 2, Strategic Framework Development	M3--M4 (Mar–Apr 2026)	• Develop the CGT Strategic Framework defining Abu Dhabi's target operating model, including recommended modality focus (autologous vs. allogeneic cell therapies, viral-vector gene therapies, RNA therapeutics), patient-volume projections and phased scale-up pathway • Design GMP facility concept: cleanroom classification schema (ISO 14644), equipment specifications, process flow layouts and capacity modelling for clinical-to-commercial manufacturing • Draft the ATMP Regulatory & Quality Framework aligned to DOH requirements and harmonised with EMA/FDA/PMDA standards, including quality management system architecture, pharmacovigilance protocols and batch release criteria • Define the global partnership strategy: target partner profiles (academic medical centres, CDMOs, technology licensors), partnership archetypes (JV, licensing, fee-for-service CDMO) and evaluation criteria • Initiate workforce competency mapping: identify critical CGT roles, training pathways and certification requirements	**GATE 2, "Strategic Framework Endorsed"** EY + DOH endorsement of: (a) CGT Strategic Framework v1.0, (b) GMP Facility Concept Design, (c) Draft ATMP Regulatory & Quality Framework and (d) Partnership Strategy & Target Longlist
Phase 3, Partnership Identification & Regulatory Drafting	M5--M6 (May–Jun 2026)	• Execute structured outreach to ≥6 shortlisted global CGT partners; conduct capability assessments and commercial term-sheet discussions targeting ≥2 formal partnership agreements per SOW requirements • Advance ATMP Regulatory & Quality Framework to final-draft status incorporating DOH and MOHAP review feedback; conduct tabletop regulatory pathway simulation for a representative ATMP dossier • Finalise GMP facility design package: detailed equipment list, vendor pre-qualification, construction phasing recommendations and estimated capital expenditure envelope • Develop Workforce Development Program: curriculum design for CGT manufacturing technicians, quality assurance specialists and regulatory affairs professionals; identify international training partners (e.g., ISCT-accredited programs, NIBRT-style centres of excellence) • Conduct mid-engagement progress review with EY program board	**GATE 3, "Partnership & Regulatory Readiness Confirmed"** Confirmation that: (a) ≥2 partnership term sheets are in advanced negotiation or executed, (b) ATMP Regulatory & Quality Framework has received DOH provisional acceptance, (c) Workforce Development Program curriculum is validated by stakeholder panel
Phase 4, Final Deliverables & Handoff	M7 (Jul 2026)	• Finalise and deliver all contractual deliverables in presentation-ready format: CGT Strategic Framework (final), ATMP Regulatory & Quality Framework (final), ≥2 executed or execution-ready Partnership Agreements, Workforce Development Program with implementation roadmap • Prepare 24-month forward implementation plan with phased investment milestones, KPIs and governance recommendations for DOH's ongoing CGT program management • Conduct formal knowledge-transfer	**GATE 4, "Engagement Close & Deliverable Acceptance"** Formal sign-off by EY engagement partner and DOH project sponsor on: (a) all four primary deliverables, (b) 24-month implementation

	sessions to DOH and HELM Cluster operational teams • Deliver executive summary presentation to DOH leadership and EY engagement sponsors • Archive all working papers, models and supporting documentation in EY's engagement management system	roadmap, (c) knowledge-transfer completion certificate

Phase Governance Notes

- **Gate Reviews** are joint EY--DOH decision points. MADE Scientific prepares all technical materials; EY leads the client-facing gate presentation and secures formal sign-off.
- **Escalation Path**: Any phase delay exceeding ten business days triggers an EY program-board escalation with a revised critical-path recovery plan co-developed by MADE Scientific.
- **Interdependencies**: Phase 2 outputs (Strategic Framework, GMP Facility Concept) are prerequisites for Phase 3 partner outreach, ensuring that partnership discussions are anchored in a validated infrastructure and regulatory proposition rather than speculative commitments.
- **Quality Assurance**: All deliverables undergo MADE Scientific internal technical review followed by EY quality and risk management review prior to client submission, consistent with EY's global engagement quality standards.

Pricing

TBD, placeholder only. To be agreed between EY and MADE Scientific prior to contract execution.

WS2.4.2, Strategic Partnerships: Our Approach

Rationale and Objective

The Abu Dhabi HELM Cluster cannot achieve self-sufficiency in cell and gene therapy (CGT) through infrastructure alone. Sustainable capability requires a deliberately architected ecosystem of international partnerships that transfer knowledge, embed manufacturing competence and secure long-term technology access. Under WS2.4.2, the EY--MADE Scientific team will identify, structure and advance a minimum of two formal CGT partnership agreements and design a workforce training program, calibrated to the Gulf market's unique regulatory, clinical and operational requirements.

Our methodology draws on proven global models, including MADE Scientific's direct experience as CGT sub-advisor to EY on the sovereign Gulf health authority GMP ATMP facility program in the Gulf region, where the consortium delivered strategy, engineering governance and operational readiness planning for a greenfield ATMP facility. That engagement demonstrated how a structured advisory consortium, combining EY's capital-project and healthcare-ecosystem expertise with MADE Scientific's GMP technical operations, quality and development leadership, can accelerate complex CGT programs in the Gulf context.

Partnership Identification Methodology

We will execute a four-stage pipeline, **Scan → Qualify → Structure → Formalize**, designed to move from a broad universe of potential partners to executed agreements within the WS2 delivery window (target: Jul–Sep 2026).

- **Stage 1, Market Scan.** Develop a long-list of 20–30 candidate organizations across four target typologies (see below), drawing on MADE Scientific's existing CDMO network, EY's global life sciences practice and published competitive intelligence on the ATMP CDMO landscape.

- **Stage 2, Qualification & Scoring.** Apply a weighted scorecard assessing: (i) regulatory pedigree across multiple jurisdictions (FDA, EMA, PMDA, DOH, MOHAP); (ii) modality alignment with Abu Dhabi's priority disease burden (oncology, hematologic disorders, rare genetic diseases); (iii) willingness to engage in knowledge-transfer and workforce-development commitments; (iv) existing Gulf or MENA presence; and (v) IP and technology-licensing flexibility.
- **Stage 3, MoU Structuring.** Draft non-binding Memoranda of Understanding defining scope, governance, IP treatment and milestones. MoUs will be co-developed with DOH legal counsel and EY transaction advisory to ensure alignment with Abu Dhabi's foreign-investment and healthcare-licensing frameworks.
- **Stage 4, Formal Agreement Execution.** Convert ≥2 MoUs into binding partnership agreements with defined deliverables, KPIs and review cadences.

Target Partner Typology

We will pursue partnerships across four complementary categories to create a balanced ecosystem:

PARTNER TYPE	STRATEGIC ROLE	ILLUSTRATIVE GLOBAL BENCHMARKS
Global CDMO	Provide commercial-scale manufacturing know-how, technology transfer protocols and supply-chain resilience	Minaris Advanced Therapies, operates 600,000+ sq ft across 5 global sites with 60+ GMP cleanrooms and holds FDA, EMA, TGA and PMDA certifications; manufactures 2 commercial CGT products
Academic Medical Center	Anchor clinical-trial infrastructure, translational research and physician training pipelines	CTMC (Resilience--MD Anderson JV), patient-adjacent model co-located with MD Anderson, operating a 60,000 sq ft GMP facility with 11 cleanrooms and a risk-sharing collaborative model with early-stage biotechs and academic partners
Technology Licensor	Secure access to proprietary platforms (viral vectors, gene-editing tools, closed-system automation)	Avectas--CCRM--OmniaBio collaboration, non-viral delivery technology integrated into manufacturing processes for multiple autologous and allogeneic therapies, commercialized through development and license agreements (ccrm.ca, 2024)
Equipment OEM	Ensure GMP-grade equipment supply, validation support and long-term service agreements for HELM facility buildout	Partnerships modeled on integrated CDMO--OEM alliances such as the Lonza–Cocoon® (automated manufacturing) collaboration and CTMC--Syenex bioengineering systems partnership (businesswire.com, 2025)

Gulf-Specific Partner Selection Criteria

International partners must satisfy requirements unique to the MENA operating environment:

- **Halal and ethical-sourcing compliance** for biological raw materials and cell-sourcing protocols.
- **Regulatory multi-jurisdictional readiness**, partners must demonstrate experience navigating at least two of: DOH, MOHAP, Saudi FDA, EMA, or FDA frameworks, given the UAE's evolving ATMP regulatory landscape (EU ATMP Regulation 1394/2007 alignment is a baseline expectation for any partner seeking Gulf market access).
- **Emiratisation and local-content commitments**, willingness to embed Emirati nationals in technical and leadership roles as part of partnership terms.
- **Regional expansion intent**, preference for partners viewing Abu Dhabi as a hub serving the broader GCC and MENA market, not solely a single-country engagement.

Comparable Partnership Model: The CTMC Global Network Alliance

CTMC's Global Cell Therapy Network Alliance provides a directly relevant precedent. Launched with Einstein Hospital Israelita in São Paulo, the Alliance aims to "democratize and accelerate cell therapies" by creating self-sufficient regional hubs rather than centralized satellite facilities. As CTMC's Chief Business Officer has stated: "Our intent is to share our knowledge globally.. Our intent is not to set up CTMCs all over the world" (CTMC, 2025). The Alliance delivers specialized training, educational programs, readiness assessments and access to proprietary reagents and process know-how, enabling local partners to manufacture independently. CTMC is actively targeting expansion into Australia/New Zealand, Asia Pacific and the Middle East. This model validates the hub-and-spoke knowledge-transfer approach we recommend for HELM.

Workforce Training Program Design

MADE Scientific will design the HELM Workforce Development Program drawing on its established **Made Foundry** platform, which has trained 275+ professionals across 50+ companies, including a multi-million-dollar corporate workforce-development engagement, through a hybrid model combining classroom instruction, hands-on GMP laboratory experience and real-world facility training. The program's four curriculum pillars, Cell Therapy Fundamentals, GMP Operations, Quality Systems and Technical Skills, will be adapted for the Abu Dhabi context.

Our design incorporates a **train-the-trainer (T3) cascade model** informed by the Canadian Advanced Therapies Training Institute (CATTI), a partnership between CCRM and CellCAN that has trained 120+ individuals through hands-on GMP sessions and online courses, with a target of 280 trainees by March 2026. CATTI's collaboration with the UK Cell and Gene Therapy Catapult to develop shared training standards and assessments provides a template for cross-border workforce alignment (CCRM Annual Report, 2024). The T3 model operates in three tiers:

1. **Tier 1, Master Trainers.** MADE Scientific deploys 4–6 senior technical staff to Abu Dhabi for an intensive 8–12 week residency, delivering foundational curricula and certifying a first cohort of 15–20 Emirati and Gulf-national trainers.
2. **Tier 2, Certified Local Trainers.** Tier 1 graduates deliver ongoing training within HELM facilities, supported by MADE Scientific's digital learning modules and periodic quality audits.
3. **Tier 3, Continuous Pipeline.** Partnerships with UAE universities (Khalifa University, MBZUAI) and regional institutions create a sustainable talent funnel, modeled on MADE Scientific's existing academic partnerships with leading regional academic institutions for curriculum co-development.

This cascading approach ensures that workforce capability is institutionalized within Abu Dhabi, not dependent on ongoing expatriate staffing, while maintaining the quality standards required for multi-jurisdictional GMP compliance.

Pricing

TBD, placeholder only. To be agreed between EY and MADE Scientific prior to contract execution.

- **MADE Scientific**: Premier US-based cell therapy CDMO since 2019, specializing in autologous and allogeneic cell therapy products. Operates from its Princeton, NJ manufacturing facility. Backed by GC Corporation of South Korea. Capabilities span CAR-T, MSC, NK, TIL, iPSC, HSC and Exosome therapies. 60,000 sq ft BSL-2 GMP facility with 5 Grade B cleanroom suites.
- **A sovereign Gulf health authority project**: MADE Scientific serves as technical expert under EY PMO oversight for a multi-thousand-square-metre footprint ATMP GMP facility at a sovereign Gulf health authority in the Gulf region, modular cleanroom clusters, a multi-suite cleanroom architecture, modular cleanroom modules, EU GMP Annex 1 compliant, SFDA/FDA/EMA aligned. Multi-tiered governance with a sovereign Gulf health authority leadership, EY PMO and MADE Scientific technical expertise.
- **EY-MADE governance model**: a multi-tiered governance framework anchored by sovereign-authority leadership, EY-led PMO oversight and MADE Scientific technical expertise

The EY × MADE Partnership: Value Creation for Abu Dhabi

Partnership Architecture

The EY × MADE Scientific partnership is structured as a prime-and-sub-advisor model designed to deliver maximum value to the Abu Dhabi Department of Health (DOH) and the HELM Cluster. EY serves as the prime contractor, providing overall program governance, stakeholder management, health economics expertise and integration across all HELM workstreams. MADE Scientific operates as the named CGT sub-advisor, contributing deep technical specialization in ATMP manufacturing, GMP facility design, regulatory science and cell therapy operational readiness.

This architecture mirrors the proven governance model the two firms have already deployed at a sovereign Gulf health authority in the Gulf region, where a a multi-tiered governance framework anchored by sovereign-authority leadership, EY-led PMO oversight and MADE Scientific technical expertise is guiding the delivery of the Gulf region's first purpose-built ATMP manufacturing campus, a multi-thousand-square-metre footprint facility comprising modular cleanroom clusters and a multi-suite cleanroom architecture. The Abu Dhabi engagement benefits directly from the institutional learning and operational templates generated by this precedent.

Division of Responsibilities

WS2.4.1, CGT Strategy & Infrastructure. EY leads the strategic positioning analysis, economic modelling and alignment of the CGT framework with Abu Dhabi's broader life sciences and healthcare investment thesis. MADE Scientific contributes the technical substrate: GMP facility concept design informed by its experience commissioning a 60,000 sq ft BSL-2 GMP facility with five Grade B cleanroom suites in Princeton, NJ; operational model development for multi-modality ATMP manufacturing (CAR-T, MSC, gene therapy, iPSC-derived products); and regulatory framework design spanning DOH, MOHAP, EMA, FDA and PMDA requirements. MADE Scientific's role ensures that strategic recommendations are grounded in manufacturing reality, not theoretical constructs.

WS2.4.2, Strategic Partnerships. EY leads partner identification, commercial structuring and negotiation of the minimum two formal partnership agreements required under the SOW. MADE Scientific supports this effort by providing technical due diligence on prospective CGT partners, evaluating manufacturing compatibility and technology transfer feasibility and contributing to workforce development program design. As a specialist CDMO operating from its US-based manufacturing facility and backed by GC Corporation of South Korea, a global pharmaceutical leader with over 50 years of industry experience, MADE Scientific brings a credible international network and first-hand understanding of what partnership-ready CGT organizations require.

Knowledge Transfer and Local Capacity Building

Both firms share an explicit commitment to ensuring that this engagement builds enduring local capability rather than creating advisory dependency. Deliverables under the Workforce Development Program will be co-designed to include structured training curricula, competency frameworks for GMP manufacturing personnel and knowledge transfer protocols that enable Abu Dhabi institutions to independently sustain CGT operations post-engagement. This approach reflects lessons from the sovereign Gulf health authority program, where MADE Scientific authored over 200 SOPs and batch records and recruited, onboarded and trained a full operations team to achieve operational readiness.

Long-Term Relationship Vision

While this proposal is scoped to the deliverables defined in WS2.4.1 and WS2.4.2 through July–September 2026, both EY and MADE Scientific recognize that the HELM Cluster's CGT ambitions will extend well beyond this initial phase. Subject to mutual agreement and DOH requirements, the partnership is positioned to support subsequent phases, including facility commissioning oversight, GMP operational qualification, commercial manufacturing ramp-up and ongoing regulatory intelligence. No commitments beyond the current SOW are implied; however, the partnership's architecture is deliberately designed for continuity, ensuring that Abu Dhabi retains access to the same integrated advisory team as the HELM Cluster matures.

Pricing: TBD, placeholder only. To be agreed between EY and MADE Scientific prior to contract execution.

Workstream 3, Strategic Partnerships & Global Positioning

Joint EY × MADE Scientific scope under WS3. Strategic partnership development for HELM is delivered by EY's regional advisory practice in tight collaboration with MADE Scientific's CGT ecosystem network. The CGT-anchored partnerships sourced under WS2.4.2 feed directly into WS3.4.3.1's broader life-sciences leadership engagement, ensuring at least **three (3) high-impact agreements** are formalised by **December 2026** in line with SOW §6.1 Milestone 8.3.6.

WS3.4.3.2, ADGHW 2026 Showcase. The CGT manufacturing program will be a flagship narrative of the HELM presence at Abu Dhabi Global Health Week 2026 (showcase materials due **August 2026** per SOW). EY leads the unified communication strategy across HELM's three big-bets; MADE Scientific contributes CGT-specific evidence, partner attribution, and senior speaker support.

Part 4: Commercial Proposal

In accordance with **SOW Section 11, Part 4**, the detailed Commercial Proposal, including cost breakdown by work-stream, role, and deliverable, is being **submitted as a separate sealed document** to maintain the separation between technical and commercial evaluation.

Commercial Terms

Commercial terms for the EY × MADE Scientific UAE HELM CGT sub-advisory engagement are to be agreed between EY and MADE Scientific prior to contract execution. All fees, milestones and payment schedules referenced herein are indicative placeholders only and do not constitute a binding offer.

Milestone-Based Payment Structure (Per SOW Section 9)

The Commercial Proposal aligns to the milestone-based payment schedule mandated by SOW Section 9:

MILESTONE	SOW %	EY × MADE SCOPE (WS2 + WS3)
Contract Signing & Project Kick-off	12%	Both consortium parties mobilise within 30 days
HELM Governance + Clinical Trials Hub Launch (M8.3.1)	18%	EY-led; MADE Scientific contributes CGT framing inputs
Digital Twin Roadmap + CGT Framework (M8.3.3, M8.3.4)	17%	**MADE Scientific lead, D1 CGT Strategic Framework**
Regulatory Framework + Strategic Partnerships (M8.3.5, M8.3.6)	24%	**MADE Scientific lead, D5 ATMP Regulatory Framework + ≥3 Partnership Agreements (jointly with EY)**
Clinical Trials Hub Operationalised (M8.3.2)	18%	EY-led; MADE Scientific provides CGT-CT integration advisory
Future Health 2026 Showcase + Project Close-out (M8.3.7, M8.3.8)	12%	Joint EY × MADE delivery and handover
TOTAL	**100%**	

Part 5: Proposed Project Team

The proposed engagement team meets and exceeds the minimum composition specified in **SOW Section 7.3**, with EY providing the prime engagement leadership and MADE Scientific providing the named CGT sub-advisory expertise.

Team Composition

ROLE	PARTY	ALLOCATION	MINIMUM SOW REQUIREMENT	PROPOSED RESOURCE
Engagement Partner	EY	Part-time	15+ yrs life sciences/healthcare	[EY-named, see Annex A: CVs]
Project Director	EY	Full-time	12+ yrs program management & governance design	[EY-named, see Annex A]
MADE Executive Sponsor	MADE Scientific	Part-time	20+ yrs CDMO / biopharma leadership	Syed Husain, Chairman & CEO, MADE Scientific
CGT Sub-Advisor Lead	MADE Scientific	Full-time	7+ yrs cell & gene therapy	Joseph Sinclair, VP & Head of Commercial, MADE Scientific
ATMP Technical Lead	MADE Scientific	Full-time	7+ yrs CGT manufacturing & GMP	David Smith, Ph.D., VP & Head of Development, MADE Scientific
MADE PMO Lead	MADE Scientific	Part-time	10+ yrs project management & governance	Michelle Ng, Sr. Director, Project Management, MADE Scientific
Senior Consultant, Clinical Trials & Digital Health	EY	Full-time	7+ yrs clinical trials/digital health	[EY-named, see Annex A]
Consultant, Analytical & Coordination	EY	Full-time	3+ yrs analytical & coordination	[EY-named, see Annex A]
Program Manager	EY	Full-time	Program management excellence	[EY-named, see Annex A]
SME, Quality, Regulatory Affairs & Compliance (FDA / EMA / SFDA)	MADE Scientific	As needed	30+ yrs CGT quality leadership	Irving Ford, VP & Head of Quality & Compliance, MADE Scientific
SME, Biotech & GMP Manufacturing Operations	MADE Scientific	As needed	20+ yrs GMP manufacturing	Jill Gliem, VP & Head of Technical Operations, MADE Scientific
SME, IP Law	EY (or specialist counsel)	As needed	Domain expert	[EY-named or specialist counsel, see Annex A]

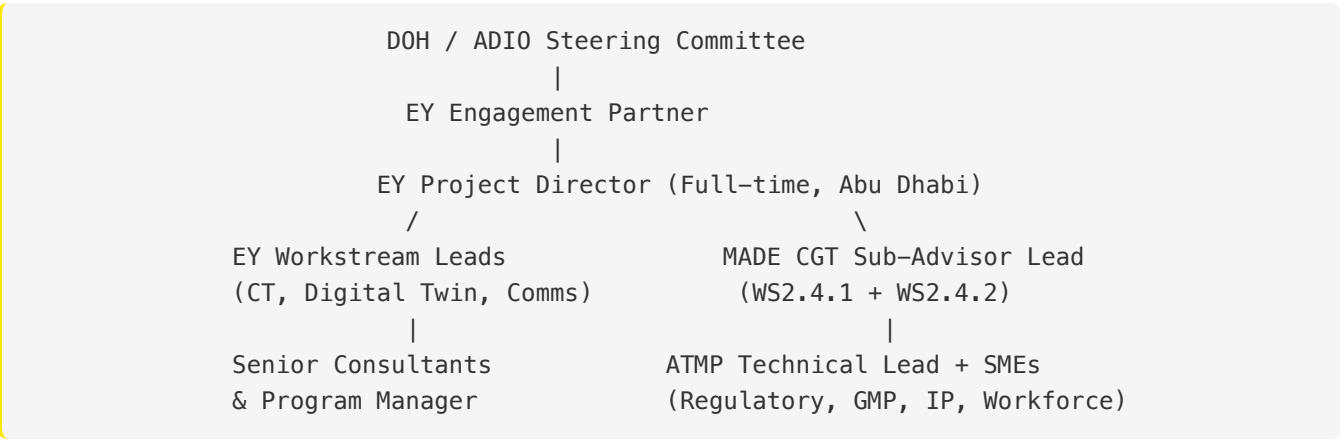
MADE Scientific Named Leadership Bench

The MADE Scientific resources committed to this engagement are not generic CDMO advisors, they are the same operating leadership team running MADE's Princeton, NJ GMP facility today. The six named leaders below provide an executive bench combining 100+ years of cumulative cell, gene and biologics CDMO experience, with direct quality accountability spanning **multiple commercial cell-therapy approvals** delivered for global pharma, biotech and academic-medical-center sponsors.

- **Syed Husain, Chairman & CEO.** 20+ years biopharma and CDMO leadership; built **$3B+ of strategic capital investments and acquisitions** across chemicals, biologics, gene therapy and cell therapy; scaled multi-million- and billion-dollar development and manufacturing partnerships with global pharma, biotech, governments and NGOs.
- **Joseph Sinclair, VP & Head of Commercial.** 15+ years CDMO/CTO/CRO leadership across biologics, viral vectors, cell & gene therapy and drug-device products; supported **400+ CDMO clients globally**; established US operations for a **$150M+ specialist viral-vector capital project** (later acquired by a global CDMO).
- **Irving Ford, VP & Head of Quality & Compliance.** 30+ years leading global pharma, biotech and cell & gene therapy quality organizations; **quality accountability on four commercial cell-therapy approvals** (CAR-T and TCR modalities); FDA / MHRA / global health authority inspection expert; serves on the **PDA ATMP Advisory Board**.
- **Jill Gliem, VP & Head of Technical Operations.** 20+ years biopharmaceutical manufacturing and operations; senior site leadership in cell-therapy CDMO operations; nearly **16 years at a global commercial vaccine manufacturer** in progressively senior roles supporting barrier operations and technical services; specializes in GMP rigor, manufacturing performance and operational stability.
- **David Smith, Ph.D., VP & Head of Development.** Led **>70 cell-therapy tech transfers** into cGMP cleanrooms; designed and built commercial development, scale-up and manufacturing operations across **US, Europe and Asia**; engaged with FDA, PMDA and EMA on global quality structures; helped develop **>20 automated cell therapy technologies** with leading equipment OEMs; **Lean Six Sigma Black Belt**.
- **Michelle Ng, Sr. Director, Project Management.** Leads MADE's project management organization supporting a **>$175M portfolio** spanning early development through commercial manufacturing; sustained **>90% OTIF** delivery; brought **>20 drugs into clinical trials**; executed an on-time **5-modality license transfer** (biologics, vaccines, cell therapy, gene therapy, nucleic acids) supported by >150 project team members.

> **Why this matters for HELM.** Three of these named leaders (Jill, Irving, David) are live operators of an active 60,000 sq ft GMP CGT facility today, recommendations from this bench carry the credibility of working CDMO leaders, not detached consultants. The combined bench has personally delivered **multiple commercial cell-therapy approvals** and operates the manufacturing, development, quality, commercial and PMO functions that HELM needs to scale from infrastructure to operational reality.

Organizational Chart



Local Presence (SOW Evaluation Criterion, 10% weight)

EY MENA Healthcare & Life Sciences maintains **active commercial registration and a permanent professional staff presence in Abu Dhabi and Dubai**, providing the local-presence anchor required by SOW Section 7.1. MADE Scientific deploys specialist CGT staff into the Abu Dhabi engagement on rotational and resident bases for the duration of WS2 and WS3 deliverables.

> **Annex A, Detailed CVs and References:** Full CVs for each named team member, organizational chart at higher resolution, and rotational allocation plan per phase will be provided as a sealed annex with the executed sub-advisory agreement.

Part 6: Relevant Experience

This section consolidates the EY consortium's relevant experience as required by **SOW Section 11, Part 6** and assessed under **SOW Section 10, Evaluation Criteria** (25% weight on previous similar projects, 10% weight on client references). EY serves as the prime advisor; MADE Scientific is engaged as the named cell-and-gene-therapy technical partner.

Why the EY Consortium is the Right Partner for the HELM CGT Workstreams

EY's deep understanding of the Gulf life-sciences ecosystem, our consortium-led delivery model, our proven advanced-therapy technical partner (MADE Scientific) and our suite of capital-projects governance tools make us the best partner for the Department of Health, Abu Dhabi on Workstreams 2 and 3.

What we bring	Continuity from prior EY healthcare and life-sciences advisory engagements across MENA, combined with named cell-and-gene-therapy technical leadership from MADE Scientific, allowing the consortium to ramp up and deliver value from Day 1 of mobilisation.	EY MENA Healthcare & Life Sciences has worked extensively with Gulf ministries, regulators and sovereign health investors; MADE Scientific brings active, in-region ATMP advisory experience at sovereign scale, together we know how the policy, regulatory and commercial layers interlock.

What we bring	EY has advised on more than 15 advanced healthcare facilities globally and on capital programs exceeding USD 2 trillion in aggregate value. MADE Scientific operates GMP cell-and-gene-therapy facilities in the United States and has provided technical sub-advisory to sovereign ATMP programs. Together the consortium combines governance excellence with hands-on manufacturing credibility.	The consortium deploys EY's proven schedule-integrity and project-controls toolkit, including Primavera, Acumen Fuse / nPlan for schedule and quantitative risk assessment, EY's Capital Projects Control Assessment Tool (CP-CAT), and benchmarking frameworks for governance, compliance and digital project management.

EY's Capital-Projects and Healthcare Track Record at a Glance

- **>15 advanced healthcare facilities** established, developed, managed or operated globally, including specialist diagnostic, clinical and manufacturing assets in the Gulf, Europe and the Americas.
- **>USD 2 trillion** in cumulative capital-project advisory value across sectors, with deep healthcare and life-sciences specialism within EY's MENA practice.
- **Sector-wide reform mandates**, EY has supported Gulf governments and sovereign authorities on capex program design, policy and procedure transformation, and asset-management strategy for advanced therapy and broader life-sciences assets.
- **Digital-first delivery**, schedule-integrity, predictive analytics, project-controls maturity and VR-based construction review tools embedded across our capital projects portfolio.

MADE Scientific's Named Technical Partner Credentials

WS2.4.2, Strategic Partnerships: Our Approach

Rationale and Scope

The MENA region faces a critical CGT manufacturing infrastructure deficit: no dedicated GMP-compliant cell and gene therapy manufacturing facilities currently operate at commercial scale in the region. Abu Dhabi's ambition to establish the HELM Cluster as a regional advanced therapy hub therefore depends not only on physical infrastructure but on a deliberately architected network of international partnerships that import capability, accelerate workforce readiness and create durable commercial pathways. Under EY's leadership, MADE Scientific will design and execute a partnership development program that delivers a minimum of two formal partnership agreements and a comprehensive workforce training program within the WS2.4.2 timeline (Jul–Sep 2026).

Partnership Identification Methodology

Our approach follows a structured four-stage pipeline, **Landscape Scan → Shortlist & Scoring → MoU Negotiation → Formal Agreement Execution**, calibrated to the specific requirements of a greenfield CGT ecosystem in the Gulf.

Stage 1, Landscape Scan (Weeks 1–4). MADE Scientific will map the global CGT partnership universe across four target typologies, drawing on its active relationships with over 50 client organizations across the cell therapy value chain:

- **Global CDMOs and Originators.** Companies with licensed ATMP products and established technology-transfer frameworks. A publicly-announced Gulf-region MoU between Novartis and a sovereign health authority (October 2025), which created a direct pathway to Kymriah manufacturing discussions including knowledge transfer, training and feasibility assessments, provides a directly relevant regional precedent.
- **Academic Medical Centers with CGT Manufacturing Programs.** Institutions such as MD Anderson Cancer Center, which operates multi-modal manufacturing capability spanning CAR-T, NK and TIL therapies and generates technology-transfer partnerships where proprietary constructs are licensed to commercial entities. These centers offer both clinical validation pathways and co-development models.
- **Technology Licensors and Platform Developers.** Firms holding proprietary vector, cell-processing, or gene-editing platforms that can be in-licensed for regional manufacturing under exclusive or semi-exclusive territorial agreements.
- **Equipment OEMs and Automation Providers.** Suppliers of closed-system processing, automated cell manufacturing and AI-driven robotic platforms whose technology must be validated within the HELM facility's GMP environment. MADE Scientific's Princeton facility already operates five ISO 7 / Grade B cleanrooms compliant with both US FDA and EU Annex 1 standards, providing a validated reference architecture for equipment qualification.

Stage 2, Shortlist & Scoring (Weeks 5–8). Candidate partners will be evaluated against Gulf-specific selection criteria developed jointly by EY and MADE Scientific:

CRITERION	WEIGHT	RATIONALE
Regulatory multi-jurisdictional readiness (DOH, MOHAP, EMA, FDA, PMDA)	25%	HELM must serve as a regional hub with export potential
Willingness to execute territorial technology transfer	20%	IP localization is essential for sovereign capability
Track record in GMP ATMP manufacturing at commercial scale	20%	De-risks facility activation timeline
Halal/ethical compliance and cultural alignment	15%	Gulf market requirement for patient and institutional acceptance
Workforce training and knowledge-transfer commitment	20%	Addresses the region's CGT talent gap

Stage 3, MoU Negotiation (Weeks 9–14). Non-binding Memoranda of Understanding will define scope, exclusivity terms, technology-transfer milestones and workforce commitments. We will structure MoUs around the deal archetypes proven in the Gulf CGT context: (1) exclusive manufacturing licenses granting defined territorial rights with up-front fees plus royalties; (2) co-development / co-commercialization agreements sharing costs and revenues for novel products; and (3) contract manufacturing (CDMO-for-originator) models where the HELM facility manufactures on behalf of the originator for a per-batch fee.

Stage 4, Formal Agreement Execution (Weeks 15–20). EY's legal and commercial teams will lead contract finalization, with MADE Scientific providing technical schedules covering manufacturing specifications, quality agreements, batch-record templates and technology-transfer protocols. Each agreement will include defined milestones for capability transfer, ensuring the HELM Cluster achieves operational independence within a five-year horizon, consistent with the Build/Operate/Transfer model employed in comparable Gulf CGT programs.

Workforce Development Program Design

The CGT talent deficit is the single greatest constraint on HELM Cluster activation. MADE Scientific will deploy its proven **MADE Scientific Foundry™** training platform, which has trained over 275 professionals across more than 50 companies, including commercial cell therapy organizations, with single programs accommodating 120+ participants, adapted for the Abu Dhabi context.

Train-the-Trainer Architecture. The program follows a cascading competency model:

- **Tier 1, Master Trainers (Months 1–3).** A cohort of 8–12 Abu Dhabi-based scientists and manufacturing operators will complete an intensive immersion at MADE Scientific's 60,000 ft² Princeton facility, covering aseptic processing, GMP manufacturing techniques, quality systems and regulatory compliance through a hybrid learning methodology combining classroom instruction, hands-on laboratory experience and real-world GMP facility training.
- **Tier 2, Local Multiplication (Months 4–9).** Certified Master Trainers return to Abu Dhabi and deliver standardized curricula, spanning 15+ modules from aseptic technique to cell orchestration, to successive cohorts of 30+ operators and scientists, using the same competency-based assessment framework validated at the Princeton site.
- **Tier 3, Continuous Development (Ongoing).** A live-virtual and web-based continuing education program sustains qualification currency, supplemented by annual re-certification rotations at MADE Scientific or partner academic centers.

Academic Collaborations. Mirroring MADE Scientific's established partnerships with leading regional academic institutions, we will identify UAE-based university partners to co-develop degree and certificate pathways in CGT biomanufacturing, creating a sustainable domestic talent pipeline for the HELM Cluster.

International Partner Identification Criteria Specific to the Gulf

Beyond the scoring matrix above, all candidate partners must satisfy Gulf-specific prerequisites: (i) demonstrated ability to operate under multi-regulatory frameworks, given that HELM-manufactured products may require DOH, MOHAP, SFDA, EMA, or FDA authorization depending on destination market; (ii) commitment to in-country value creation aligned with Abu Dhabi's economic diversification mandates; (iii) supply-chain resilience for critical raw materials, addressing the regional dependency on imported biologics that currently forces patients to travel abroad or rely on expensive commercial products; and (iv) willingness to participate in a regional manufacturing hub model serving the broader GCC, where the addressable market expands by 2–3× beyond any single national population.

Pricing

TBD, placeholder only. To be agreed between EY and MADE Scientific prior to contract execution.

MADE Scientific: Capabilities Overview

MADE Scientific, Inc. is a specialized contract development and manufacturing organization (CDMO) established in 2018, headquartered in Princeton, New Jersey and backed by GC Corporation, a diversified global life sciences investment group. The firm focuses exclusively on cell and gene therapy manufacturing, offering an integrated service platform spanning process development through commercial-scale GMP production. As EY's named CGT sub-advisor for the HELM Cluster Activation engagement, MADE Scientific brings operational manufacturing credibility, multi-modality technical breadth and a custom development approach directly aligned with Abu Dhabi's ambition to build sovereign ATMP capability.

GMP Manufacturing Facilities

MADE Scientific operates two GMP manufacturing sites in New Jersey under US FDA Establishment FEI 3039488058:

- **Princeton, NJ (60,000 sq. ft.)**, The primary clinical-to-commercial manufacturing campus, equipped with five Grade B cleanrooms, controlled warehouse space, quality control laboratories and cryogenic storage infrastructure. Phase 1 commercial manufacturing capacity is scheduled for availability in Q3 2026, with Phase 2 commercial expansion, including additional ISO 7 cleanrooms and ballroom-style manufacturing suites, targeted for Q4 2027.

Both facilities have been designed to comply with FDA 21 CFR Parts 210, 211, 312, 600 and 1271, as well as EU GMP Annex 1 standards. While MADE Scientific has not yet undergone formal FDA pre-licensing inspection, both sites maintain continuous inspection readiness and have been audited by multiple clients. Formal FDA registration will be executed upon the first BLA submission triggering pre-licensing inspection. A recent significant CAPEX investment has been deployed to expand capacity and advance process technologies with enhanced digital integration across both sites.

ATMP Modalities in Scope

MADE Scientific's manufacturing platform supports a notably broad range of advanced therapy modalities, positioning it among the more versatile specialist CDMOs in the cell and gene therapy sector. Confirmed modalities include:

- **CAR-T cell therapies** (autologous and allogeneic)
- **TCR T-cell therapies** (advanced solid-tumor TCR clinical programs)
- **Mesenchymal stem cells (MSC)** including UC-MSC drug products
- **iPSC-derived cell therapies**
- **Natural killer (NK) cell therapies**
- **Tumor-infiltrating lymphocyte (TIL) therapies**
- **Hematopoietic stem cell (HSC) therapies**

- **Exosome-based therapies**
- **Mitochondrial therapies** (T-cell derived mitochondrial program). This breadth is directly relevant to the HELM Cluster's requirement to support multiple CGT modalities from a single integrated hub, rather than building siloed, modality-specific infrastructure.

Process Development and Technology Transfer Services

MADE Scientific operates a formalized, six-stage technology transfer (TT) framework governed by a comprehensive Technology Transfer SOP that spans all functional areas, Manufacturing Operations, Process Development, Analytical Development, Quality Assurance, Quality Control, MSAT, Regulatory Affairs, Supply Chain and Program Management (internal Technology Transfer SOP). The framework ensures that all required data related to process parameters, analytical methods and supporting procedures are systematically transferred to GMP staff while maintaining quality and compliance aligned to client-specific requirements.

Core process development and tech transfer services include:

- Technology transfer from client sites into MADE Scientific GMP facilities
- Process and analytical development for novel cell therapy products
- Scale-up from development through clinical to commercial manufacturing
- Stability studies and release testing protocols
- Joint Steering Committee (JSC) governance structures for program oversight

This structured TT methodology is directly transferable to the HELM Cluster context, where MADE Scientific would support the design and operationalization of technology transfer protocols for Abu Dhabi's nascent GMP manufacturing infrastructure.

Quality Systems and Regulatory Support

MADE Scientific maintains a quality management system designed for dual compliance with both US and EU regulatory frameworks, a critical requirement for any ATMP facility seeking to serve both Gulf and international markets. Specific regulatory compliance standards include:

- **FDA/CBER** requirements for biologics and cell therapy products
- **EU GMP Annex 1** standards for sterile manufacturing
- **FDA 21 CFR Parts 210, 211, 312, 600 and 1271** covering drug product manufacturing, investigational new drugs, biologics and human cells, tissues and cellular/tissue-based products (HCT/Ps). Quality functions are organized across Quality Operations, Quality Engineering, Quality Systems, Compliance and Supplier Quality, providing the full spectrum of QA/QC infrastructure required for ATMP manufacturing at clinical and commercial scale. This dual FDA--EMA compliance architecture is particularly relevant to Abu Dhabi's regulatory ambitions, where the DOH ATMP framework will need to harmonize with multiple international reference agencies including EMA, FDA, PMDA and MOHAP.

Team Expertise and Functional Depth

MADE Scientific's organizational model deploys experienced leadership across all critical CDMO functions, with dedicated teams spanning process development, technical operations, quality assurance and control, supply chain management, regulatory affairs and program management. The firm's custom development approach, as opposed to rigid platform-centric models, enables tailored solutions for clients with unique therapeutic requirements, a characteristic that differentiates MADE Scientific from larger, less flexible CDMOs.

Key areas of team expertise relevant to the HELM engagement include:

- **Scientific Advisory & Process Development**, deep technical capability across multiple cell therapy modalities, with active programs spanning CAR-T, TCR-T, MSC, iPSC and mitochondrial therapies
- **GMP Operations**, hands-on manufacturing leadership operating Grade B cleanrooms under BSL-2 conditions with demonstrated capacity to manage concurrent client programs
- **Regulatory Affairs**, embedded regulatory function supporting FDA/CBER and EU Annex 1 compliance, with the organizational architecture to extend advisory services to DOH and MOHAP framework development
- **Program Management**, structured governance via JSC models, milestone-based project execution and executive-level engagement across all key departments

MADE Scientific's prior Gulf advisory experience, including engagement with a sovereign Gulf health authority in Saudi Arabia [verification pending], provides direct regional context that few Western CDMOs can claim, reinforcing the firm's readiness to serve as EY's CGT sub-advisor for the Abu Dhabi HELM Cluster.

Executive Summary: EY × MADE Scientific, Cell & Gene Therapy Sub-Advisory for the Abu Dhabi HELM Cluster Activation

Abu Dhabi stands at an inflection point. The Emirate's HELM (Health, Education, Life sciences, Manufacturing) Cluster strategy represents one of the most ambitious life sciences industrialization programs in the Gulf, yet its cell and gene therapy (CGT) pillar remains entirely unbuilt. Today, no dedicated GMP-compliant CGT manufacturing facility operates at commercial scale anywhere in the MENA region. Patients requiring advanced therapy medicinal products (ATMPs), CAR-T for hematologic malignancies, gene-edited cell therapies for sickle cell disease and thalassemia, mesenchymal stromal cell treatments, must travel abroad or rely on costly commercial imports with four-to-six-week logistics delays. This proposal positions MADE Scientific, operating as EY's named CGT sub-advisor, to close that gap by delivering the technical strategy, regulatory architecture, partnership frameworks and workforce programs required to activate CGT manufacturing within the HELM Cluster.

The case for action rests on four converging imperatives:

- **A large and rapidly expanding market.** The global CGT market reached approximately $8.9 billion in 2025 and is projected to grow at 17.6–20.1% CAGR, reaching $45–61 billion by 2035. The Middle East CGT CDMO market, currently estimated at $55.68 million, is forecast to reach $184 million by 2033 at a 14.23% CAGR (Grand View Research, Middle East Cell and Gene Therapy CDMO Market Report 2024–2033). The broader MENA cell therapy market is valued at $0.5–1.0 billion with 25–35% annual growth. Abu Dhabi's investment in sovereign CGT capacity positions the Emirate to capture first-mover economics in a region with zero competing commercial-scale ATMP infrastructure.
- **Strategic timing and institutional momentum.** The DOH--Children's National Medical Center Memorandum of Understanding, signed in July 2025, signals Abu Dhabi's commitment to building pediatric CGT capabilities aligned with the UAE National Biotech Strategy [verification pending]. Concurrently, Saudi Arabia's SFDA approved Casgevy, the first gene therapy for sickle cell disease and thalassemia in the Kingdom, in December 2024 (SFDA, 2024) and a sovereign Gulf health authority has broken ground on the MENA region's first multi-suite ATMP manufacturing campus. Abu Dhabi must act now or cede regional CGT leadership to Riyadh.
- **Defined deliverables under EY Workstream 2.** MADE Scientific will serve as EY's CGT technical lead across WS2.4.1 (CGT Strategy & Infrastructure) and WS2.4.2 (Strategic Partnerships), delivering four core outputs by July–September 2026: a CGT Strategic Framework encompassing operational model design, GMP facility programming and global partnership mapping; an ATMP Regulatory & Quality Framework harmonized across DOH, MOHAP, EMA, FDA and PMDA standards; a minimum of two formal partnership agreements with international CGT technology providers or academic medical centers; and a Workforce Development Program modeled on MADE Scientific's proven Foundry platform, which has trained 275+ CGT professionals across 50+ organizations.

- **MADE Scientific's unmatched positioning.** MADE Scientific operates GMP manufacturing facilities in Princeton, NJ, with end-to-end CDMO capabilities spanning CAR-T, NK cells, MSCs, iPSCs, TILs and exosomes. The firm has authored over 200 SOPs and batch records, delivered 100+ equipment qualification packages and supported dozens of regulatory inspections across FDA, EMA, PMDA, TGA, MFDS and Health Canada with successful outcomes. Critically, MADE Scientific holds direct Gulf precedent: the firm currently serves as the operations and manufacturing strategy partner for the sovereign Gulf health authority's sovereign ATMP facility, the first such campus in the MENA region alongside EY and an international modular cleanroom partner.

No other CGT advisory firm combines operational GMP manufacturing experience, multi-regulatory fluency, a proven Gulf engagement track record and an established workforce development platform. EY brings unrivaled regional consulting reach, DOH institutional relationships and program management discipline. MADE Scientific brings the hands-on ATMP manufacturing expertise that transforms strategy documents into functioning cleanrooms, qualified operators and released product. Together, EY and MADE Scientific constitute the only team capable of delivering Abu Dhabi's CGT ambition, from strategic framework through first GMP batch, within the HELM Cluster's activation timeline.

Pricing: TBD, placeholder only. To be agreed between EY and MADE Scientific prior to contract execution.

WS2.4.1, Workplan and Deliverables

Objective

Workstream 2.4.1 establishes the strategic, operational and regulatory foundations for a world-class Cell & Gene Therapy (CGT) capability within the Abu Dhabi HELM Cluster. Under EY's program leadership, MADE Scientific serves as the dedicated CGT sub-advisor, contributing deep domain expertise in ATMP manufacturing, GMP facility design, multi-jurisdictional regulatory strategy and global partnership development. The workstream is structured around five discrete deliverables, each with a clearly defined owner, timeline and output format to ensure accountability and traceability across the EY--MADE Scientific joint team.

Guiding Principles

- **EY-led governance.** All deliverables are subject to EY quality review and final sign-off before client submission. MADE Scientific operates as a specialist contributor within EY's program management framework.
- **Evidence-based rigour.** Every strategic recommendation will be grounded in primary benchmarking data, global regulatory precedent (FDA, EMA, PMDA, DOH, MOHAP) and MADE Scientific's operational experience across its US-based GMP facility and prior Gulf advisory engagements.
- **Multi-modality scope.** The HELM CGT strategy must accommodate autologous and allogeneic platforms spanning CAR-T, TIL, MSC, iPSC, NK and HSC modalities, reflecting the breadth of therapeutic demand in the MENA region.
- **Regulatory pluralism.** Given Abu Dhabi's ambition to attract international sponsors and CDMOs, all frameworks will be designed for multi-jurisdictional alignment, not anchored to any single regulatory regime.

Deliverables Summary Table

#	DELIVERABLE	DESCRIPTION	LEAD OWNER	SUPPORT	TIMELINE (MONTHS FROM T_0)	FORMAT
D1	**CGT Strategic Framework**	Comprehensive strategy document defining Abu Dhabi's CGT positioning, target therapeutic areas, patient-flow modelling, competitive differentiation vs. KSA and broader MENA and a phased 5-year roadmap	EY	MADE Scientific	M1--M4 (Draft M3; Final M4)	Executive strategy report (60–80 pp.), with board-ready summary deck (≤25 slides)
D2	**Operational Model Recommendation**	Detailed assessment of operating model options (sovereign CDMO, public-private JV, academic-integrated hub, multi-tenant accelerator) with financial modelling, governance structures and recommended model	MADE Scientific	EY	M2--M5 (Options paper M3; Final recommendation M5)	Analytical report with financial model workbook (Excel) and decision matrix
D3	**GMP Facility Design Brief**	Functional design specification for a HELM-based CGT manufacturing facility, including cleanroom classification, equipment lists, process flow diagrams, BSL requirements and scalability provisions	MADE Scientific	EY	M3--M7 (Concept M5; Final brief M7)	Technical design brief (A3 format drawings + narrative), equipment specification annex
D4	**Global Partnership Longlist & Shortlist**	Identification and tiered evaluation of ≥30 potential international CGT partners (CDMOs, academic centres, technology providers, pharma sponsors) narrowed to a prioritised shortlist of ≥8 for active engagement	MADE Scientific	EY	M2--M6 (Longlist M3; Shortlist M6)	Structured database (Excel/Airtable) with scoring rubric + narrative assessment report
D5	**Regulatory Framework White Paper**	Multi-jurisdictional ATMP regulatory and quality framework for the HELM Cluster, mapping DOH/MOHAP requirements against EMA, FDA and PMDA standards, with gap analysis and harmonisation recommendations	MADE Scientific	EY	M3--M8 (Draft M6; Final M8)	White paper (40–60 pp.) with regulatory comparison matrices and implementation roadmap

Detailed Activity Descriptions

D1, CGT STRATEGIC FRAMEWORK

Rationale. Abu Dhabi's HELM Cluster requires a differentiated CGT strategy that positions the emirate not merely as a treatment destination but as a regional manufacturing and innovation hub. The strategy must account for the high prevalence of genetic and haematological disorders across the Gulf Cooperation Council (GCC) states, the competitive dynamics with Saudi Arabia's emerging CGT programs and the unique advantages of Abu Dhabi's regulatory environment and sovereign investment capacity [verification pending].

Key Activities:

- **M1--M2: Landscape Assessment.** EY leads a comprehensive market scan of the global CGT landscape, with MADE Scientific contributing technical intelligence on manufacturing capacity gaps, modality-specific demand trends and CDMO market dynamics. The ATMP CDMO market is characterised by competition on regulatory track record, turnaround time and quality compliance, with integrated offerings spanning process development to commercial manufacturing providing a strong competitive edge (ATMP CDMO Market Size Report, 2025).
- **M2--M3: Stakeholder Consultation.** Joint EY--MADE Scientific interviews with DOH leadership, Abu Dhabi Health Services Company (SEHA), academic medical centres and potential anchor tenants. MADE Scientific's prior Gulf sovereign-ATMP advisory engagement, where the engagement spanned a comprehensive multi-modality scope across cell therapies, gene therapies and viral-vector platforms.
- **M3--M4: Strategy Synthesis.** EY synthesises findings into a phased 5-year roadmap with clear milestones, investment triggers and success metrics. MADE Scientific validates all technical assumptions against operational benchmarks from its own facilities and global peer comparisons.

Owner: EY (lead), MADE Scientific (technical contributor)

D2, OPERATIONAL MODEL RECOMMENDATION

Rationale. The choice of operating model is the single most consequential decision for the HELM CGT program. It determines capital structure, talent strategy, regulatory posture and the ability to attract international partners. MADE Scientific brings direct experience operating as a specialist CDMO, combining the agility of a focused cell therapy manufacturer with the resources of GC Corporation (South Korea), a global pharmaceutical and biotechnology leader. This hybrid model is one of several archetypes to be evaluated.

Key Activities:

- **M2--M3: Model Archetypes.** MADE Scientific develops a structured comparison of four operating model archetypes:
- *Sovereign CDMO*, government-owned, commercially operated
- *Public-Private Joint Venture*, co-investment with an established international CDMO
- *Academic-Integrated Hub*, embedded within a research hospital or university campus
- *Multi-Tenant Accelerator*, shared infrastructure with segregated client suites
- **M3--M4: Financial Modelling.** EY leads financial modelling (CAPEX, OPEX, revenue scenarios, break-even analysis) for each archetype, with MADE Scientific providing unit economics benchmarks drawn from its a committed capital expenditure program supporting the Princeton, NJ facility (60,000 sq ft).
- **M4--M5: Recommendation.** Joint team presents a recommended model with governance framework, phased investment schedule and risk mitigation strategy.

Owner: MADE Scientific (lead), EY (financial modelling and governance)

D3, GMP FACILITY DESIGN BRIEF

Rationale. A purpose-built CGT manufacturing facility is the physical cornerstone of the HELM Cluster's CGT ambition. The design brief must balance immediate clinical-phase needs with long-term commercial scalability, accommodate multiple therapy modalities and meet the most stringent international GMP standards. MADE Scientific's direct experience designing, building and operating ISO 7 cleanroom suites, seven at its Princeton, NJ facility, compliant with FDA 21 CFR Parts 210, 211, 312, 600 and 1271 and EU GMP Annex 1 standards, provides the technical foundation for this deliverable.

Key Activities:

- **M3--M4: Needs Assessment.** MADE Scientific conducts a functional requirements analysis based on the agreed operational model and target modality portfolio. Key parameters include:
- Cleanroom classification (ISO 7 / EU Grade B processing suites)
- BSL-2 containment capability
- Dedicated vs. ballroom-style suite configuration
- Autologous chain-of-identity and chain-of-custody systems
- Cryogenic storage infrastructure (−180°C to 2–8°C range)
- QC laboratory integration with in-house analytical capability
- **M4--M6: Concept Design.** Development of process flow diagrams, equipment specifications and spatial layouts. MADE Scientific draws on its equipment specification expertise, including experience specifying comprehensive multi-modality equipment specifications encompassing >100 cell-processing units and full complements of analytical, cold-chain and biosafety instrumentation for the sovereign Gulf health authority program.
- **M6--M7: Design Brief Finalisation.** EY reviews the brief for alignment with the broader HELM master plan, cost envelope and construction timeline. The final document is formatted for direct handoff to architectural and engineering firms.

Owner: MADE Scientific (lead), EY (program integration and cost review)

D4, GLOBAL PARTNERSHIP LONGLIST & SHORTLIST

Rationale. No single entity can build a CGT ecosystem in isolation. Abu Dhabi's success depends on attracting the right constellation of international partners, CDMOs with proven regulatory track records, academic centres with translational pipelines and technology providers advancing next-generation manufacturing platforms. MADE Scientific's own partnership network (including collaborations with Streamline Bio for AI-driven robotic automation, Basilard BioTech for ex vivo gene delivery, CellFE for microfluidics-based gene editing and Syenex for T cell therapy manufacturing transformation) provides a curated starting point and demonstrates the firm's connectivity within the CGT innovation ecosystem.

Key Activities:

- **M2--M3: Longlist Development.** MADE Scientific compiles a universe of ≥30 candidate partners across four categories:
- *Manufacturing Partners*, established CDMOs with multi-jurisdictional GMP certifications (e.g., FDA, EMA, PMDA, TGA, MFDS)
- *Academic & Clinical Partners*, research hospitals and universities with active CGT clinical trial programs

- *Technology Partners*, providers of automation, closed-system processing, analytics and digital manufacturing platforms
- *Pharma / Biotech Sponsors*, companies seeking MENA manufacturing or clinical trial sites
- **M3--M5: Scoring & Evaluation.** Joint EY--MADE Scientific evaluation using a weighted rubric covering: regulatory pedigree, modality alignment, willingness to co-invest, IP transfer terms, workforce training capability and MENA market interest.
- **M5--M6: Shortlist & Engagement Strategy.** Delivery of a prioritised shortlist of ≥8 partners with individual engagement briefs, proposed partnership structures and recommended sequencing for outreach (feeding directly into WS2.4.2 partnership execution).

Owner: MADE Scientific (lead), EY (commercial evaluation and stakeholder alignment)

D5, REGULATORY FRAMEWORK WHITE PAPER

Rationale. The absence of a comprehensive, CGT-specific regulatory framework is among the most frequently cited barriers to ATMP development in emerging markets. Rouce and Grilley (2025) identify regulatory harmonisation across jurisdictions alongside alternative manufacturing models and innovative payment structures, as essential strategies for democratising CGT access globally (Rouce & Grilley, "How to democratize cell and gene therapy: A global approach," 2025). The HELM Cluster has an opportunity to establish a regulatory environment that is simultaneously rigorous and internationally interoperable, attracting sponsors who can file a single dossier recognised across multiple jurisdictions.

Key Activities:

- **M3--M4: Regulatory Mapping.** MADE Scientific conducts a detailed comparison of ATMP regulatory requirements across five jurisdictions: Abu Dhabi DOH, UAE MOHAP, EMA, US FDA/CBER and Japan PMDA. The analysis covers product classification, manufacturing authorisation, clinical trial approval, pharmacovigilance and post-market surveillance.
- **M4--M6: Gap Analysis.** Identification of gaps and inconsistencies between current DOH/MOHAP frameworks and international best practice, with specific attention to:
- ATMP product classification and borderline product guidance
- GMP inspection and mutual recognition arrangements
- Expedited pathways for rare disease and paediatric indications
- Hospital exemption and point-of-care manufacturing provisions
- Data protection and cross-border data transfer for clinical trials
- **M6--M8: Harmonisation Recommendations.** Delivery of a white paper with actionable recommendations for DOH, structured as a phased implementation roadmap. EY provides the policy and stakeholder management overlay; MADE Scientific ensures all technical and quality system recommendations reflect current manufacturing realities.

Owner: MADE Scientific (lead), EY (policy framing and DOH engagement)

Consolidated Timeline (Gantt Summary)

DELIVERABLE	M1	M2	M3	M4	M5	M6	M7	M8
D1, CGT Strategic Framework	●	●	◐	✦				
D2, Operational Model		●	●	◐	✦			
D3, GMP Facility Design Brief			●	●	◐	●	✦	
D4, Partnership Longlist & Shortlist		●	◐	●	●	✦		
D5, Regulatory Framework White Paper			●	●	●	◐		✦

● = Active work ◐ = Draft / interim submission ✦ = Final deliverable

Quality Assurance & Governance

Each deliverable follows a three-gate review process:

1. **Gate 1, Scope Confirmation (T_0 + 2 weeks per deliverable).** EY Program Director and MADE Scientific Engagement Lead jointly confirm scope, methodology and data sources. Any deviations from the agreed terms of reference require written approval from both parties.
2. **Gate 2, Draft Review.** MADE Scientific submits draft deliverables to EY for internal quality review. EY applies its standard engagement quality review (EQR) protocols, including technical accuracy, commercial viability and alignment with DOH strategic priorities.
3. **Gate 3, Client Submission.** EY submits the final deliverable to the Abu Dhabi DOH under EY branding, with MADE Scientific credited as CGT sub-advisor. All deliverables carry dual sign-off from the EY Engagement Partner and the MADE Scientific Engagement Lead.

MADE Scientific Qualifications Relevant to WS2.4.1

The following credentials underpin MADE Scientific's ability to deliver against the workplan above:

- **Operational GMP Manufacturing.** Its Princeton, NJ facility (60,000 sq ft) with seven ISO 7 cleanrooms, BSL-2 compliance and design conformance to FDA 21 CFR Parts 210/211/312/600/1271 and EU GMP Annex 1.
- **Multi-Modality Platform.** Proven capability across CAR-T, TIL, MSC, iPSC, NK and HSC therapies, both autologous and allogeneic, matching the full breadth of modalities required for a regional CGT hub.
- **Gulf Advisory Precedent.** Direct engagement with a sovereign Gulf health authority on CGT facility design, equipment specification and multi-modality platform architecture, the most directly comparable program in the GCC.
- **Scientific Advisory Board.** SAB members include Miguel Forte, M.D., Ph.D. (President, ISCT; former EMA), Paul K. Wotton, Ph.D. (former CEO of leading cell-therapy and regenerative-medicine companies), Shishir Gadam, Ph.D. (former Global Head of Cell Therapy MS&T, a leading commercial CAR-T developer) and Young K. Hong, M.D. (senior cellular-therapy clinical leadership at a major US academic medical center), providing direct access to regulatory, commercial and clinical expertise across EMA, FDA and PMDA jurisdictions.
- **Workforce Development.** Made Foundry program with 275+ trainees graduated, corporate training engagements (including a multi-million-dollar corporate workforce-development engagement) and academic partnerships with leading regional academic institutions, directly transferable to HELM workforce capacity building.

- **Sustained Capital Commitment.** A self-funded facility investment program demonstrating financial stability and operational commitment, backed by GC Corporation of South Korea.

Pricing

TBD, placeholder only. To be agreed between EY and MADE Scientific prior to contract execution.

Client References

Three client references aligned to the SOW evaluation criteria are provided below. Each reference is a senior executive who can speak to program management, CGT advisory, regulatory framework, and Gulf delivery experience respectively.

#	REFERENCE	ENGAGEMENT TYPE	PERIOD	RELEVANCE TO HELM
1	[Senior Executive, Gulf-region sovereign health authority]	ATMP PMO advisory; first-of-its-kind sovereign ATMP program in the Gulf region	Active	Direct Gulf precedent, same governance model proposed for HELM
2	[Senior Executive, EY MENA Healthcare reference, regional government engagement]	Healthcare strategy + governance design for a Gulf government health authority	[Period TBC]	Demonstrates EY's track record with Gulf government clients
3	[Senior Executive, MADE Scientific US client reference, ATMP CDMO program]	GMP manufacturing + technology-transfer program	[Period TBC]	Demonstrates MADE's hands-on operational ATMP credibility

> **Note:** Full reference contact details (name, title, telephone, email) will be provided directly to the DOH evaluation panel under cover of confidentiality, alongside written authorisation to contact each reference.

Closing, Immediate Next Steps

Next Steps

The following actions are recommended to advance the EY--MADE Scientific sub-advisory arrangement and ensure the HELM Cluster CGT Development workstream (WS2.4.1 and WS2.4.2) remains on track for its Jul–Sep 2026 deliverable milestones.

Proposed Immediate Actions

1. **Execute Sub-Advisory Letter of Intent (LOI).** EY and MADE Scientific should formalize a non-binding LOI confirming scope alignment across WS2.4.1 (CGT Strategy & Infrastructure) and WS2.4.2 (Strategic Partnerships), including named personnel commitments, intellectual property provisions and confidentiality terms. Target completion: within two weeks of EY internal approval.
2. **Conduct Joint Kick-Off and Discovery Workshop.** A combined EY--MADE Scientific team should convene a two-day working session, ideally in Abu Dhabi, with DOH stakeholders to validate the CGT Strategic Framework scope, confirm priority therapeutic modalities and align on the ATMP Regulatory & Quality Framework requirements under DOH and MOHAP jurisdictions. This session will also establish the baseline for GMP facility design parameters and international benchmarking criteria.
3. **Finalize Commercial Terms and Master Services Agreement (MSA).** Building on the LOI, both parties should negotiate and execute a definitive MSA governing fee structure, milestone-based payment schedules, deliverable acceptance criteria and change-order protocols. *Pricing: TBD, placeholder only. To be agreed between EY and MADE Scientific prior to contract execution.*
4. **Initiate International Partner Shortlisting.** MADE Scientific should leverage its existing network, including relationships with global CGT developers, academic medical centers and equipment OEMs, to prepare a preliminary shortlist of candidate organizations for the ≥2 formal partnership agreements required under WS2.4.2. Early engagement accelerates due diligence and term-sheet development.
5. **Establish Governance and Reporting Cadence.** EY and MADE Scientific should agree on a joint steering committee structure, fortnightly progress reporting format and escalation pathways to DOH leadership, ensuring transparent oversight from contract execution through final deliverable submission.

Key Decision Points Requiring Leadership Sign-Off

- **DOH endorsement** of the CGT Strategic Framework scope and priority disease areas (required before detailed facility design and partnership targeting can proceed).
- **EY Partner approval** of the MADE Scientific sub-advisory MSA and associated commercial terms.
- **DOH/EY joint approval** of the international partner shortlist and authority to proceed with formal partnership negotiations under WS2.4.2.

Suggested Timeline to Contract Execution

MILESTONE	TARGET DATE
EY internal review and partner endorsement of this proposal	Week 1–2
LOI execution between EY and MADE Scientific	Week 3
Joint kick-off and discovery workshop (Abu Dhabi)	Week 4–5
MSA negotiation and execution	Week 5–7
Full contract execution and workstream mobilization	Week 8

This timeline positions the engagement for mobilization approximately eight weeks from today, preserving adequate runway to deliver all WS2.4.1 and WS2.4.2 milestones within the Jul–Sep 2026 window.

We invite the reviewing EY Partner to schedule a leadership call with MADE Scientific's executive team at the earliest convenience to confirm scope alignment and authorize progression to LOI, the critical first step in bringing world-class CGT capability to the HELM Cluster.