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David Mix Calls for Collective Action to Bring Cell and Gene Therapies Within Patientsâ?? Reach

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The Programme Director of Act For Hope discusses how shared manufacturing standards, stronger referral pathways and practical knowledge exchange could help translate scientific breakthroughs into wider patient access.



Cell and gene therapies are redefining treatment possibilities, yet fragmented manufacturing processes, complex referrals and reimbursement barriers continue to limit patient access. In an interview with **BioSpectrum Asia**, **David Mix, Programme Director of Act For Hope**, explains how the member-driven social enterprise is bringing patients, clinicians, developers and industry partners together to address these challenges. He outlines its priorities for manufacturing standardisation, access infrastructure and knowledge sharing, alongside initiatives aimed at building a more connected and equitable advanced therapies ecosystem.

What prompted the creation of Act for Hope, and which gaps in the cell and gene therapy ecosystem are you seeking to address first?

The single greatest failure of the biopharma sector today is the number of proven, life-saving or altering therapies that exist in a lab or a clinical trial today, while a patient dies waiting on red tape, referral delays, or because of prohibitive costs. The barrier is more than just scientific, it is systemic. We need to build something better, together.

Act for Hope was born out of this stark reality: despite extraordinary breakthroughs in cell and gene therapy, the global infrastructure required to deliver these treatments to patients remains fragmented, costly, and painfully slow. Too often, early-stage innovators, academic developers, commercial manufacturers, and healthcare centers operate in silos. They re-learn the same hard lessons from scratch, encounter similar regulatory hurdles, and duplicate expensive validation efforts. Every time an organization solves a known problem in isolation, patient access is delayed.

Act for Hope was established as a member-driven, zero-profit social enterprise to serve as the tactical bridge-building special forces unit operating behind the scenes. We could not maintain a passive position when action can save lives. Comprised of 60 high level people and organisations across all elements of the forefront of CGT development, Act for Hope is building the data bridges, standardized workflows, and access frameworks where others encounter dead ends.

Our immediate focus is directed at three critical friction points across the ecosystem. First, we are tackling unstandardized manufacturing release criteria, such as inconsistent Certificate of Analysis expectations, which inflate batch costs and create regulatory confusion. Second, we are breaking down siloed knowledge transfer so emerging biotechs do not waste precious capital on avoidable technical mistakes. Finally, we are working to streamline fragmented patient access pathways and administrative referral red tape that prevent eligible patients from reaching specialized treatment centers in time.

With 60 members across 11 stakeholder groups, how will Act for Hope turn such diverse perspectives into practical action rather than another industry discussion forum?

The name Act For Hope was chosen by our members because of stagnation the industry experienced after the significant initial market boom, and because our members made a pact to represent action. Furthermore, every project we undertake is guided by a core question: can our collective expertise, representing centuries of industry experience, expedite processes and rapidly improve patient outcomes?

Rather than hosting passive discussion, we channel the work of our sixty members, including bioprocess engineers, clinicians, developers, regulators, payers, investors, and patient survivors, dedicated, deliverable driven workstreams focused on work products that will find utility in the system at multiple levels. We need diverse working groups because the process of moving advanced therapies requires interdisciplinary teams that can share perspective on how project components can support or affect the different focus areas of each team. To build a bridge over hurdles, a team must understand what has been built before, and demonstrate why new work will make the system more equitable and efficient for all, and not just corner another segment of the market or create a new silo.

Our approach emphasizes bringing those that, in the absence of collaborative guiding principles, might compete for the sake of competing. On neutral, pre-competitive ground, Act for Hope is establishing baseline specifications and standards, mapping referral networks, aligning pre-competitive infrastructure that serves the entire rising tide rather than individual commercial Intellectual Property. Crucially, by embedding patient recipients and advocates directly into technical working groups alongside developers and payers, we ensure that our outputs directly solve real-world patient delivery challenges rather than remaining abstract academic exercises.

Patient access remains one of the biggest challenges for cell and gene therapies. What specific barriers are you prioritising, and how do you intend to address them?

Act for Hope is prioritizing research and understanding confounding and interdependent barriers that can create insurmountable challenges in the patient journey. But these barriers must be understood in the context of the fragmented payer system, particularly in the US where private payers may or may not agree to cover costs. The Fail First, step therapy paradigm is being addressed with our advocacy partners as we continue to build data-sharing projects that can bring diversity to the marketplace and thereby bring overall costs down.

One persistent systemic issue we are addressing is where and how referrals are made, and how accreditation is achieved. Patients facing life-threatening conditions are frequently identified too late or become trapped in complex administrative referral chains between clinics and accredited tertiary hospitals. Through our Access and Accreditation Workstream, we are conducting in-depth studies on referral networks and cost barriers while working hand-in-hand with accreditation partners like FACT and regional payers to harmonize onboarding criteria and reduce administrative friction without compromising safety.

Another barrier is ecosystem fragmentation, and lack of awareness. We are currently planning and developing education strategies to support both providers and patients. Patient advocates, clinicians, and developers are often unaware of existing access initiatives, compassionate use programs, or regional support frameworks operating in isolation. To solve this, our Patients Workstream is building the Industry Initiatives Portal, a centralized digital hub that maps, connects, and amplifies access and reimbursement initiatives across the CGT landscape, enabling stakeholders to align around shared priorities and scale proven solutions.

Manufacturing capacity, cost and scalability continue to constrain CGT adoption. Where do you see the greatest opportunities for industry-wide collaboration?

The single greatest opportunity for industry-wide collaboration lies in the standardization of specifications, processes, and best practices, and knowledge sharing. We shouldn't have to reinvent the wheel every time a new therapy is poised to reach the market. These information silos drive up costs and maintain an inequitable and unsustainable marketplace when

the costs to develop these life saving medicines continue to be measured in the billions.

Because the "starting material" is a living cell collection from a sick patient or donor, the entire manufacturing pipeline must adapt to the biology of that specific batch. Autologous cell therapy manufacturing currently suffers from batch-to-batch variability, custom analytical assay requirements, and inconsistent Certificate of Analysis expectations across regulatory jurisdictions. This lack of standardization inflates the cost of goods sold and creates prolonged vein-to-vein turnaround times that directly impact patient survival.

By collaborating on pre-competitive baselines, the industry can achieve transformative gains. Harmonizing Certificate of Analysis standards, for example, across cell therapies and viral vectors allows developers and contract manufacturers to streamline validation and regulatory filings. Establishing guidelines for raw material risk mitigation reduces batch failures, while building open-access data frameworks enables emerging developers to benchmark validation data. This collective intelligence accelerates the broader industry shift toward automated, closed-system point-of-care production and scalable allogeneic platforms.

The United States, has historically invested heavily in research, and in spite of its political uncertainties, and changes at the FDA, is likely to continue to be a major engine for investment, while China has developed a coherent long-term manufacturing and engineering investment strategy.

What initiatives or measurable outcomes should the CGT community expect from Act for Hope over the next 12–18 months?

Over the next 12 to 18 months, the CGT community can expect tangible tools and data bridges from Act for Hope. Notably, we will share key publication milestones for our Certificate of Analysis Tables White Paper ahead of its 2027 release. This initiative will likely consider standardized release criteria frameworks, reagent risk mitigation strategies, and analytical method qualification guidelines.

Alongside our manufacturing work, we will launch the Industry Initiatives Portal, establishing a single source of truth to map global CGT access and reimbursement efforts to prevent duplicated work across the ecosystem. Simultaneously, our Access and Accreditation Workstream will publish empirical studies detailing referral network bottlenecks and accreditation cost structures to help health systems improve access. Our Knowledge Sharing Workstream expands practical toolkits helping early-stage biotechs navigate tech transfer and contract manufacturing partnerships efficiently.

We anticipate the launch of the Act For Hope Academy, where members will have access to additional topical guidelines on how to navigate barriers, and create more efficient and cost effective journeys to help get products to the marketplace. As we build out curriculum needs and prioritize learning outcomes, we will launch a webinar series where top industry subject matter experts will share best practices and practical solutions to creating project plans, all of which will be archived on the member platform.

Finally, a collaboration platform is in the research and development phase. This platform will systematized data sharing, and allow other members to work on projects together more seamlessly. Product developers shouldn't have to go on a scavenger hunt to assemble manufacturing systems and gather critical information on basic requirements. At Act For Hope, we can leverage our networks and proven collaborative capacity to actively contribute to each other's projects.

Looking towards 2027, what changes do you expect to see in the global CGT landscape, particularly around access, manufacturing and commercialisation?

Looking toward 2027, Act For Hope members anticipate a major structural evolution across access, manufacturing, and commercialization, creating a more diverse marketplace. Act For Hope members hope to play a significant part in this revolution. In market access, health systems will shift away from rigid, upfront list-price reimbursement toward amortized healthcare annuities, milestone-based installment payments, and harmonized health technology assessments, such as the EU Joint Clinical Assessment. Multi-regional real-world data registries will become standard practice, providing the continuous clinical evidence required to support outcomes-based risk-sharing models globally.

In manufacturing, production will move decisively toward standardized, automated, and closed-system processing. As clarity around release specifications improves through industry-wide initiatives, batch turnaround times will shorten dramatically, and second-generation allogeneic therapies will begin lowering commercial costs toward sustainable levels.

Finally, commercialization strategies will abandon isolated regional launches in favor of integrated, multi-regional rollout networks supported by unified accreditation frameworks and digital portals that align clinicians, payers, and patients from day one.

The number of patients treated compared to the billions invested in CGTs themselves is a terrible indictment of the entire sector. Whilst many bigger organisations have tried and failed in the past, Act For Hope believes that operating as a smaller special forces operation, with the flexibility to make changes warranted by the changing circumstances within the quickly evolving sector, will be the way to move forwards and actually, finally, get therapies to widespread patient groups in a cost-effective format. In a world where entropy is the norm, and cynicism is common, and me must endeavor to understand the failure points, we are determined to reassemble the pieces of a broken puzzle and make something beautiful that is more reminiscent of our potential than our possessions.