

ARRIGE Statement on Universal CARTs – 23 January 2026

Genome-edited cellular therapies: scientific breakthroughs, renewed ethical-legal urgency for accessibility and equity

The recent publication of two independent clinical studies reporting the use of genome-edited allogeneic CAR T cells—one in T-cell acute lymphoblastic leukemia (Chiesa et al. NEJM, January 2026) and one in recurrent high-grade glioma (Li et al. Nature Communications, January 2026)—marks a significant scientific milestone in the field of advanced therapies. These studies demonstrate, for the first time in patients, the feasibility and early clinical promise of universal, genome-edited CAR T-cells, including delivery via non-standard routes such as intrathecal administration.

From a scientific perspective, these advances directly address some of the structural bottlenecks identified during ARRIGE’s 2025 international annual meeting that was dedicated to the cost and global accessibility of genome-edited therapies. In particular, the transition from autologous to allogeneic, off-the-shelf CAR T products represents a potential inflection point for scalability, manufacturing standardization, and ultimately cost reduction. By reducing individualized production, vein-to-vein time, and batch-specific regulatory complexity, such approaches may contribute to more sustainable delivery models, provided that affordability and access are explicitly embedded upstream.

From an ethical and legal perspective, this shift from bespoke, patient-specific manufacture to banked, allogeneic products also alter the normative expectations placed on health systems. A therapy that is scalable by design strengthens claims grounded in the right to health and the principle of justice, once technical feasibility and standardization are achieved, persistent exclusion increasingly reflects policy choices rather than unavoidable scarcity. Universal CAR T models therefore transform not only manufacturing paradigms, but also the ethical baseline against which access failures must be judged.

However, these publications also reinforce a central message that strongly emerged during the ARRIGE meeting: technological progress alone will not guarantee equitable access. Despite their promise, genome-edited CAR T therapies remain among the most complex and resource-intensive interventions in contemporary medicine. Their clinical deployment continues to rely on highly specialized infrastructure, advanced regulatory oversight, proprietary genome-editing platforms, and concentrated technical expertise, factors that collectively risk deepening existing global inequities in access.

This complexity has direct legal implications. Regulatory pathways, hospital accreditation standards, pharmacovigilance obligations, and long-term follow-up requirements effectively function as gatekeepers of access. Where legal frameworks do not explicitly integrate equity objectives, such as geographic coverage, referral rights, and public financing guarantees, technological innovation risks being filtered through administrative and institutional barriers that reproduce existing inequalities.

The two newly published trials exemplify a broader ethical tension discussed extensively at the ARRIGE annual meeting: while innovations such as universal CAR T cells may improve scalability in high-income settings, they do not automatically translate into accessibility for low- and middle-income countries, or even for underserved populations within wealthy health systems. Without deliberate governance, pricing strategies, and capacity-building efforts, the transition from autologous to allogeneic products may shift, but not resolve the fundamental access gap.

From a global (justice) perspective, this raises questions about states' extraterritorial responsibilities in the governance of transformative biomedical technologies. When advanced therapies are developed through transnational scientific networks and publicly funded research ecosystems, ethical responsibility cannot end at national borders. Without coordinated regulatory reliance, technology transfer, and equitable licensing strategies, universal CAR T therapies risk becoming universal in name but geographically exclusive in practice.

Reinforcing lessons from the ARRIGE annual meeting

These developments give renewed urgency to several conclusions articulated during the meeting:

- Affordability must be designed, not retrofitted. Decisions related to genome-editing platforms, delivery technologies, manufacturing models, and intellectual property taken at early stages will decisively shape future access and the legal feasibility of reimbursement, public procurement, and inclusion in national benefit packages. Where access planning is absent at the design stage, later attempts at equity are constrained by intellectual property, regulatory exclusivities and entrenched commercial models.
- Innovation incentives and equity remain in tension. The proprietary nature of genome-editing tools and CAR T constructs continues to raise questions about licensing practices, public return on public investment, and corporate responsibility. This tension is not only ethical but juridical. Public investment in genome-editing platforms and CAR T development raises questions about legal conditions of funding, public-interest licensing, and the enforceability of access commitments.
- Health systems are ill-equipped for high upfront, curative-intent therapies. Even if long-term benefits are substantial, current reimbursement and financing models remain poorly adapted to therapies requiring large advance payments. This inadequacy is not merely financial, but structural. Many legal frameworks for reimbursement, health technology assessment, and insurance coverage are built around chronic or incremental therapies, not high-cost, one-time interventions. Without legal reform, financing rules themselves become barriers to access.
- Rare diseases collectively constitute a major public health burden. Universal CAR T approaches may expand indications, but they also amplify the ethical question of how societies prioritize and finance high-cost interventions affecting relatively small patient populations.

In light of these new clinical advances, ARRIGE reiterates its commitment to promoting an ethical framework in which equity is a foundational principle of scientific progress, not an

afterthought. Genome-edited cellular therapies hold extraordinary promise, but realizing their societal value will require:

- Early integration of access and affordability considerations into research and development
- Transparent international governance and cost-sharing mechanisms
- Equitable licensing and technology-transfer strategies
- Sustained inclusion of low-resource settings in scientific, regulatory, and policy deliberations
- Development of regulatory and reimbursement pathways for advanced therapies that explicitly embed equity, including criteria for geographic access, referral rights, public financing, and long-term patient protection.

As emphasized during the annual meeting, the question is no longer whether genome-edited therapies can transform medicine, but whether the global community is willing to ensure that they do so justly. The emergence of universal, genome-edited CAR T cells marks a turning point in the moral economy of advanced therapies. When innovation becomes scalable, continued exclusion is no longer ethically neutral or legally incidental. It becomes a question of governance: who designs the rules of access, who benefits from public investment, and whose lives are deemed worth the cost of cure.

ARRIGE will continue to contribute to this effort through ethical-legal analysis, policy-relevant research, and international dialogue, with the aim of supporting innovation that serves not only scientific excellence, but also global health equity.

The ARRIGE Board

References

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2. [Intrathecal CRISPR-edited allogeneic IL-13R \$\alpha\$ 2 CAR T Cells for recurrent high-grade Glioma: preclinical characterization and phase I trial.](#)

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