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Reported Patient Death in an Innovative CRISPR Trial

Clinical Holds and Trial Governance: Practical Takeaways for Israeli Biotech Sponsors

Client Update - January 2026

Dear Clients,

Recent public reporting described a serious adverse event in a Phase 3 clinical program using an in vivo CRISPR-based approach, including the reported death of a trial participant. The same reporting noted subsequent U.S. FDA clinical hold activity affecting related Phase 3 trials (click here).

For Israeli biotech companies, which often operate with lean in-house teams and rely heavily on CROs and specialty vendors across jurisdictions, this type of event serves as a reminder that a single safety event can rapidly evolve into a multitrack company issue requiring coordinated action across clinical, regulatory, quality, legal and investor/partner communications.

This update highlights practical governance and readiness points that Israeli sponsors may wish to consider, particularly where clinical operations and data are distributed across vendors and jurisdictions.

Why this matters in practice

Innovative modalities and first/early-in-class programs tend to draw heightened attention from regulators, partners, and diligence teams. When a serious adverse event occurs, these can trigger parallel workstreams under time pressure. These typically include immediate operational decisions under the protocol, coordinated communications with vendors and sites, regulatory engagement, and the creation and control of a consistent factual record that can withstand review.

Key practical takeaways for Israeli sponsors and management teams

1. Escalation pathways and decision authority need to work under time pressure.

   When a serious safety event occurs, companies may need to pause screening, enrollment, dosing, or shipments under the protocol, convene the relevant safety governance, and initiate regulator facing workstreams, sometimes before a full medical picture is available. Clear internal ownership (medical lead, clinical operations, QA, regulatory, legal) and pre-defined decision pathways reduce delay, inconsistent messaging, and fragmented documentation.

2. Vendor coordination is often the bottleneck.

   In many Israeli biotech trials, the CRO and specialized vendors (labs, pharmacovigilance, imaging, depot, biostatistics) are the primary holders of operational information and "first drafts" of narratives and reports. The practical question is not only what the agreements say, but whether the company has an operationally workable playbook for urgent safety scenarios: who drafts the initial narrative, who owns medical review, who approves submissions and how fast turnaround is achieved. Companies should also confirm that vendors can support accelerated regulator engagement (including rapid retrieval of source-like materials, data listings, and audit trails where relevant).

3. Documentation becomes the backbone of regulator engagement and diligence

   In a clinical hold, contemporaneous documentation can become as important as the underlying clinical facts. Israeli companies should assume that safety narratives, decision logs, DSMB interactions, vendor communications, and regulator correspondence may later be reviewed in diligence, audits, or inspections. A disciplined approach to version control, document retention, and fact management can materially reduce the risk of later inconsistencies.

4. Data and Safety Monitoring Board processes should be ready for inspection and due diligence

   Where a DSMB is in place, the practical value comes from clarity on scope, information flows, timelines, and documentation. Companies should confirm that the DSMB charter is operationally workable; that meeting minutes and recommendations are properly documented; and that sponsor actions in response to DSMB recommendations are recorded.

5. External communications benefit from consistency across jurisdictions

   Safety events can generate pressure to communicate quickly, sometimes while facts are still being evaluated. A practical goal is to ensure that public statements, investor updates, partner communications, and regulator-facing narratives are aligned with documented facts and are consistent over time. This is particularly sensitive for Israeli public companies (TASE, NASDAQ, dual-listed) or companies in active fundraising/partnering, where disclosure decisions may be scrutinized and where inconsistent phrasing can create avoidable friction later.

Who should pay particular attention

This update may be particularly relevant to Israeli companies running US focused or multi-jurisdictional clinical trials, companies developing products using novel modalities, companies relying on CROs and multiple specialty vendors across jurisdictions, and companies anticipating major diligence events (partnering, M&A, crossover financing, IPO readiness) where clinical governance and documentation are evaluated.

Suggested next steps companies may wish to consider

1. Run a short targeted readiness review focused on SAE escalation, decision authority, and documentation controls.

2. Review CRO and key vendor arrangements for urgent safety event workflows, reporting timelines, and cooperation obligations.

3. If applicable, confirm that the DSMB documentation package is complete and operationally workable.

4. Stress test internal processes for regulator correspondence and other external communications, including drafting, review, approvals, and version control of the factual record.

Legal Counsel

The information provided in this client update is for general informational purposes only and should not be construed as legal advice or a substitute for professional legal counsel.

We remain at your disposal to provide legal counsel on any matters arising from the developments described above and to assist as needed.

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