

Communicating about an unexpected immune response in a clinical trial involving gene editing within a hospital setting – Scenario F

Case Study to Guidance for Communicating on Gene Technology 2025¹

A major hospital is running Australia's first clinical trial of a gene editing therapy for an inherited cardiomyopathy. Initial results show promising efficacy but reveal an unexpected immune response in 30% of participants. The immune response indicates a previously unidentified risk, but it is manageable with current treatments, and the clinical trial will continue.

The principal investigator (PI), clinical team, hospital management and trial sponsor must quickly communicate with the participants and prospective participants, as well as hospital administrators, regulators, and media.

Previously, the hospital's communications department had promoted this research as "groundbreaking", and several trial participants have shared their experiences on social media.

How should the hospital team — and in particular the Principal Investigator (PI), who is a gene-editing expert, and a sponsor — communicate the unexpected finding? How can they communicate in a way that upholds scientific integrity, aligns with research ethics committee requirements, and continues to earn participant trust, and public confidence in gene therapy research?

Hypothetical Responses to the Guiding Questions

1. What is your purpose or goal (i.e., why do you want to communicate) and on what time scale do you hope to achieve that goal?

The hospital team seek to:

- Ensure that participants, prospective participants, regulators, governance bodies and other researchers are aware of the unexpected immune response, what it means for the health of the participants, and how it will be monitored and managed going forward. The PI understands that sharing this information widely is essential for patient safety, participant informed consent, and for the future development of gene editing therapies.
- Explain how the decision to continue the trial was made — the PI believes that transparency will help preserve trust in the trial and future gene-editing research.
- Moderate previous communications from the hospital that may have portrayed experimental gene editing therapies as more fully developed than they are.

The hospital team agree they need to communicate immediately, prioritizing trial participants and regulatory authorities... *(the reader, on further reflection, may have additional responses)*

2. With whom do you wish to engage—that is, who is your audience or target?

¹ Gene Technology Ethics & Community Consultative Committee [Guidance for Communicating on Gene Technology 2025](#)

The hospital team intends to reach a broad audience, including:

- Trial participants and their families (first priority).
- Regulatory authorities.
- Cardiomyopathy patient advocacy groups.
- Funding agencies and philanthropic and commercial partners.
- Scientific peers and medical media.
- General media and the broader public who have followed earlier promotional stories.

They understand that they will need to tailor communication to the different audiences...

3. How can you ensure that your communication is transparent and that you are open about assumptions and uncertainties, benefits and risks?

The hospital team plan to:

- Give an explanation of the risks, using real numbers. For example, 3 of 10 participants to date had a moderate immune response, and all of them improved after receiving steroid therapy. The team intend to provide a formal risk-balance statement to the regulatory authorities.
- Explain remaining uncertainties and outline the plan to monitor future related risks in lay terms...

4. Are you communicating based on your specific expertise, and what evidence will you use to ensure that your claims are accurate and can be externally fact checked?

The hospital team understands that running a clinical trial of gene editing therapy for cardiomyopathy relies on different types of expertise. They plan to consult with these different experts when developing their communication to ensure its accuracy. The experts who will be consulted include:

- The lead immunologist for safety data and information on the outcomes of similar trials.
- The Hospital Chief Medical Officer for institutional risk controls.
- The cardiologist.

They plan to use reliable data sources — either formal trial records or scientific publications...

5. How can you move away from simply giving people information — which assumes that the problem is their lack of knowledge and has been shown to rarely work — and instead, have two-way conversations and shared reflection between you and the target audience?

The hospital team are considering the following ways to facilitate conversations with the target audiences:

- A virtual town-hall for participants, support persons and patient advocates with live polling to set discussion priorities, and anonymous questions.

- Assigning a response coordinator.
- Establishing a phone line and dedicated email address for queries, managed by experts drawn from the clinical trials team...

6. What forms of media and forums are the best for communicating your message and why?

The hospital team knows that they will need different media and forum for different audiences. They consider:

- Virtual town halls, e-mails and webinars for initial disclosures to participants for privacy and to allow nuanced communication.
- Pre-prints and a webinar hosted by a professional society for the clinical research community.
- A press release, including an infographic explaining immune responses and mitigation, for the media and publics.
- The PI will also be available for media interviews...

7. What values, meanings, attitudes, beliefs, or other underlying considerations should be articulated when crafting your communication plan and the language used within it?

The hospital team:

- Are aware that different audiences have different interests and adjust communication accordingly. For example, participants and their families — who may be hoping for a cure for inherited cardiomyopathy — will react very differently to news of the unexpected immune response than scientific colleagues, who are focused on advancing the technology.
- Will explicitly talk about their commitment to patient safety, transparency, learning from setbacks, and ethical stewardship.
- Avoid terms such as ‘breakthrough’ that may create a false picture of an experimental therapy’s safety and efficacy. Instead, they will use precise, lay descriptions of the purpose of the clinical trial and the therapy it is testing, and outcomes to date...

8. Given the rapid pace of developments in gene technology research, how can your communication strategy be designed to remain relevant and valid for as long as possible?

The hospital team will keep their communications relevant and valid by:

- Scheduling weekly safety reviews and update all stakeholders immediately.
- Nominating a team member to track related international trials and integrate new findings into future briefings...

9. What are likely to be the most effective and ethical strategies for communicating about gene technology in the face of mis/disinformation and fake news?

The hospital team may:

- Acknowledge that earlier communications framed the gene editing therapy as a breakthrough and explain their preference for more matter-of-fact descriptions of what they know about the experimental therapy.
- Release data about the unexpected immune response with plain English explanations and supporting figures in accordance with established protocols for conveying adverse event information.
- Monitor social media for mis/disinformation and provide clarifications if needed.
- Coordinate with national cardiovascular and genetics advanced therapy societies to provide accurate information.
- Provide access to an expert, which may be a patient advocate, to answer questions from journalists and prospective participants about the gene editing therapy and related technologies...

Version Control Table:

Version	Author	Date	Changes
1.0	GTECCC	15/12/2025	Version 1.0 Final