FALLING
WALLS
CIRCLE

PLENARY TABLE "ALTERING MEDICINE BY CELL AND GENE THERAPY"

The creation of innovative medicines using cells and genes as therapeutic agents greatly profits from the ongoing technological progress. Innovation happens across academia and industry and collaboration in manufacturing, clinical validation and market entry is crucial for the development of novel therapies that benefit healthcare. The experts of this Falling Walls Circle discuss the learnings from exemplary innovation hubs, key success factors of co-development and co-creation and how collaborations between academia, start-ups and industry can better serve patients' particular needs and advance societal and economic sustainability.

Panelists: Maria Alfaiate (Bayer, DE), Hildegard Büning (Medizinische Hochschule Hannover, DE), Sarah Hedtrich (Berlin Institute of Health at Charité, DE), Debora Lucarelli (Enhanc3D Genomics, UK), Wolfram-Hubertus Zimmermann (University Medical Center Göttingen, DE), and moderator Johannes Fruehauf (BioLabs, US).

KEY TAKEAWAYS

1. **Collaboration drives innovation in medicine.** With the first approval of a gene-edited drug expected in the US in 2024, novel gene therapies are on the rise. This massive innovation in healthcare is the result of a decade-long collaboration between academia, start-ups, and the industry, who translated medical findings into innovative therapies and products. The experts on this panel highlight the importance of ongoing collaborative efforts in the future. Bayer's initiative to establish a cell and gene translation centre in collaboration with the Charité and the city of Berlin can be seen as best practice. It exemplifies this collaborative approach, focusing on scalability while preparing healthcare systems for new treatments.

2. **Respect the challenges in gene and cell therapies.** While novel therapies hold promise for various diseases beyond monogenic conditions, such as infectious diseases and cancer, making them accessible and maintaining safety standards remains challenging. Scientists need to be aware and inform patient organisations, regulators, and clinicians about the benefits and risks of these therapies. They need to bridge the gap between preclinical research and clinical application through innovative approaches. "As researchers, we need to show the public and clinicians who we are and what exactly we are doing, without bias and in a radical open fashion", says Hildegard Büning.

3. **Consider regulatory standards and engage stakeholders early.** Current healthcare systems may not be prepared for the new paradigm shift in medicine. Thus, the panelists emphasise the need for the early involvement of stakeholders from both the healthcare system and regulatory authorities. It is necessary to navigate diverse legal frameworks and opinions within the EU, such as the reimbursement systems or risk-sharing agreements that are already common in the US and UK, says Wolfram-Hubertus Zimmermann: "Regulatory authorities have to be involved very early and especially in the EU, where different countries with different opinions and legal frameworks have to be taken into account."

This event is supported by Bayer & Berlin Institute of Health at Charité.