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The translation of fundamental research discoveries into cell and gene based medicinal products

The therapeutic potential of cell and gene therapies has created a great deal of excitement in a range of biomedical fields. The path from fundamental research, through to licensing applications involves several important components. These include, studies assessing the validity of critical concepts, pre-clinical potential safety and efficacy studies, the design of clinical trials, production of products that are suitable for clinical investigations. Similarly important is the process leading to regulatory authorisation of clinical studies, the efficient conduct of meaningful clinical investigations, proof of concept and pivotal trials through to licensing applications. These processes constitute a complex path, with multiple critical steps and potential bottlenecks, involving important design and implementation challenges. In an open discussion forum, some of the most prominent of these challenges will be identified and strategies to address them will be examined.

Biography

Farzin Farzaneh holds the Chair of Molecular Medicine at King's College London. He has published over 250 research articles with an average citation of over 30, and an Impact Factor of 47. He has run a licensed GMP facility at King's College London, since 2001, for the production of cell and gene therapy based investigational medicinal products. Farzin has extensive industrial and academic collaborations, including research council, charitable and pharmaceutical sponsorships of £25M. He has initiated a number of clinical trials in novel applications of gene therapy and holds MHRA licences (IMPs and "Specials"). He is a Qualified Person (QP) for release of cell and gene therapy products in UK and EU and an Individual Designate under a Human Tissue Authority licence that allows procurement, testing, processing, distribution and/or import/export of tissues and or cells intended for human applications. He is also appointed by the Commission on Human Medicines, as a member of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group since 2016.

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