
FEBS National Lecture

Lectures

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Lessons learnt, and still to learn, in *in human* stem cell trials

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We are now entering an era in which increasing numbers of stem cell-based therapies are being trialed in first-in-human (FIH) studies. In this presentation, we show some of the key issues that should be considered in such translational work, ideally beginning with the initial therapeutic concept and the scientific rationale for the therapy. This prospective approach from the outset of the work also greatly facilitates the chance of an in-human trial being acceptable to regulatory authorities without the need to go back to the drawing board. In addition, such a forward-thinking approach brings with improved opportunities for funding support and a return on investments without compromising the scientific integrity of the work. The areas chosen to concentrate on in this presentation are not exhaustive, but have been chosen based on our experiences in translating therapies to clinic and include many things we wished we had known when we started.