NSC-Reconstruct

NSC-Reconstruct Workshop #2: Regulatory and ethical issues related to the development and clinical use of next generation cell therapy products

November 22nd-23rd, 2021

all timing below in Central European Time (CET)

November 22nd - Day 1, 14.00-18.00:

Development of a cellular product for clinical use
(20+10 min for each presentation)

14.00 – 14.10 Elena Cattaneo (*Milan, Italy*): **Welcome and Introduction**

14.10 – 14.40 Tina Zinck
Novo Nordisk, Regulatory Affairs Director in the Cell Therapy R&D
Overview of the regulatory process – what is needed to document in the CTA relating to the cell product

14.40 – 15.10 Melissa Carpenter (online)
Elevatebio, Cambridge, MA, USA
Importance of selecting the starting material

15.10 – 15.40 Agnete Kirkeby (*Copenhagen, Denmark*)
Manufacturing of a GMP compatible product using StemPD as a case

15.40 – 16.00 BREAK

16.00 – 16.30 Malin Parmar (*Lund, Sweden*)
Characterisation of the product, safety and efficacy using StemPD as a case

16.30 – 17.00 Lorenz Studer (online)
Memorial-Sloan Kettering Cancer Center, New York City, USA
Experiences from interactions with the FDA

17.00 – 18.00 Discussion: regulatory requirements from different national authorities

Dinner in the evening

19.15 Dinner at Ihsiri (Bytaregatan 14, 222 21 Lund)

November 23rd - Day 2, morning session, 9.00-12.30:

Development of a first-in-human clinical trial
(20+10 min for each presentation)

09.00 – 09.30 Emma Cutting (*Cambridge, UK*)
Overview of the regulatory process - what is needed to document in the CTA relating to clinical trial design and execution

09.30 – 10.00 Roger Barker (*Cambridge, UK*)
Trial design, incl patient selection, endpoints and sham surgery - using StemPD as a case

10.00 – 10.30 Nicholas Lao-Kaim (online)
Imperial College London
How to explore graft survival and efficacy using imaging tools

10.30 – 10.50 BREAK

10.50 – 11.20 Alasdair Coles
University of Cambridge, UK
Ethical aspects

11.20 – 11.50 Håkan Widner with patient (*Lund, Sweden)*
Patient perspective

11.50 – 12.30 General Discussion

12.30 – 13.30 LUNCH

Day 2, afternoon session, 13.30-15.30:

Development of a commercial product
(20+10 min for each presentation)

13.30 – 14.00 Klaus Langhoff-Roos
Novo Nordisk - CVP in stem cell-based therapies commercial
How do you assess the commercial value of a cell product/program?

14.00 – 14.30 Graziella Pellegrini
University of Modena and Reggio Emilia, Emilia-Romagna, Italy
Experiences from the development of a clinical product

14.30 – 15.00 Andreas Bosio (*Bergisch Gladbach, Germany*)
How can improvements in a cellular product be introduced in an ongoing clinical program?

15.00 – 15.30 Concluding Discussion