



Future Targeted Healthcare Manufacturing Hub Healthcare Specialist Working Group

Healthcare: Reimbursement & Regulation

Friday 11th October 2019, 10:00-14:45

UCL Dept. Biochemical Engineering - Bernard Katz Building, London WC1E 6BT

Agenda

10:00 Coffee

10:30 Welcome and introductions

10:40 Introduction to Healthcare SWG

Prof Steve Morris & Dr Irina Brass

10:45 Challenges of Highly Specialised Technologies (HSTs)

Guest speaker: Sheela Upadhyaya, Associate Director, National Institute for Health and Care Excellence (NICE)

11:15 Meeting regulatory demands for ATMPs manufacturing and controls

Dr Houria Bachtarzi, Senior Consultant, Regulatory Affairs, Gene and Cell Therapies, ERA Consulting

11:45 Future Targeted Healthcare Manufacturing Hub Public Policy Landscape

Dr Penny Carmichael, Hub Policy Advisor

12:20 Hub Researchers updates on finding

12:20 Reimbursement: How to facilitate outcomes-based reimbursement of ATMPs

Nishma Patel

12:30 Regulators' support for innovation: opportunities and limits

Dr Giovanni De Grandis

12:50 Discussion

13:00 Lunch

13:30 Roundtable discussion to help shape Hub research

1. Regulatory strategies for ATMPs (*chairs: Giovanni De Grandis, Irina Brass*)

- a) Optimising developers-regulators interactions
- b) How to improve characterization and controls?
- c) What to expect from automation and closed systems?

2. Reimbursement for ATMPs (*chairs: Nishma Patel, Steve Morris*)

- a) Objectives of outcome-based payment and operational challenges
- b) The advantages of new registries for evidence generation
- c) Core principles governing real world data collection (NHS perspective)

14:30 Suggestions for future workshops

14:45 Close