CGT/CT-TRACS Workshop

Wed 14th February 2018

Title:	**Safety assessment of cell therapy products: current advances and challenges.**
Time:	9:00 – 15:00 *Workshop* 15:00 – 17:00 *Networking event*
Location:	29th floor Tower Wing, Guy's Hospital, Great Maze Pond, SE1 9RT, London (guy's map)

AGENDA		
8.30 – 9.00	Arrival/registration – *Breakfast*	
9.00-9.10	Welcome and Introduction	Dr Michaela Sharpe, CGT.
	Challenges, gaps and needs to assess the safety of cell therapy products	
9.10 – 9.35	Regulatory Perspective (I)	Dr Carla Herberts, Medicines Evaluation Board, NL; CT-TRACS Co-Chair
9.35 – 10.00	Regulatory Perspective (II)	Dr James McBlane, MHRA, UK
10.00-12.20	**Tumorigenicity session**	
10:00– 10:25	Scheme of MEASURE, a Japanese PPP experimental consortium for standardization of tumorigenicity testing methods	Dr Keiji Yamamoto, Takeda/FIRM, Japan
10:25 – 10:50	*In vitro* testing methods for detection of tumorigenic cellular impurities in pluripotent stem cell-derived products	Dr Yoji Sato, NIHS, Japan
10.50 – 11.05	*Coffee Break*	
11.05 – 11:30	*In vivo* tumorigenicity testing for pluripotent stem cell-derived products.	Dr Takatoshi Koujitani, Sumitomo Dainippon Pharma, Japan
11.30- 11.55	iPSC genomic instability and impact on product safety.	Prof Peter Andrews, University of Sheffield, UK

11:55 – 12:20	Case studies presentations, challenges, gaps and needs to assess the safety of cell therapy products – the CDI experience.	Dr. Genevieve Gowing, Cellular Dynamics International, USA
12.25 – 13.15	*Lunch*	
13.15 – 15.00	**Biodistribution and Imaging session**	
13.15 – 13:40	Industry perspective.	Dr. Bill Singleton, GE Healthcare, UK; CT-TRACS Co-Chair
13.40 – 14.05	Multimodal clinical cell tracking.	Dr. Mangala Srinivas, Radboud U., NL
14.05 – 14.30	Monitoring the fate of administered cells using whole body radionuclide imaging.	Prof. Phil Blower, KCL, UK
14.30– 14.55	Challenges of non-clinical and clinical development for CAR-T cell therapies – the Autolus experience.	Dr. Shimobi Onuoha, Autolus, UK
15.00 – 17.00	**Networking event (all)** **Tumorigenicity Business meeting (by invitation)**	

Topics & Learning objectives:

1) **Future needs in patient safety of cell-based therapies.** Identify challenges and opportunities to enhance the accuracy and efficiency of safety assessment of cell therapy products. Perspectives from a broad range of stakeholders from design to implementation settings.

2) **Evolving safety tools and applied safety techniques.** Learn about *in vivo* cell tracking approaches and their role in supporting clinical translation, as well as methods for evaluating the potential tumorigenicity risk of cell-based therapeutic products.

3) **Role of collaboration in cell therapy development and use.** Explore international opportunities to bridge stakeholders and improve our ability to develop and implement and effective standards.