

Cambridge Alliance on Medicines Safety

Translation of Safety in the Clinic

Virtual event
Monday 19th June
2023
12.30-16:30 GMT

Translation of clinical safety with new modalities:

- Lessons learnt from gene therapy and cell therapy
- Leveraging data to get an early indication of risk



Agenda:

12:30 Introduction. *Marion MacFarlane*
(MRC Toxicology Unit)

Session 1: Preclinical to clinical translation

- ▶ **12:35** Current approaches for advanced therapy medicinal products. *Chris Powell* (CBPC)
- ▶ **13:00** Modelling safety preclinically: CAR-T cell case study. *Attilio Bondanza* (AstraZeneca)
- ▶ **13:25** Clinical monitoring and translation in early development for new modalities. *Magnus Nord* (AstraZeneca)

Session 2: Pharmacovigilance in the clinic

- ▶ **14:00** Pharmacovigilance: MHRA perspective and the Yellow Card Biobank. *Alison Shaw* (MHRA)
- ▶ **14:25** Collecting genomic data in clinical trials to inform safety and efficacy: a case study. *Mike Chapman* (MRC Toxicology Unit/Addenbrookes)
- ▶ **14:50** Clinical Drug Safety in Cell Therapy Trials. *Jon Renninger* (GSK)

15.25 All speakers – Round table discussion.
Chair: Stephanie Ling (AstraZeneca)

16.00 Q&A and online Networking

