

# ***Translational Pharmacology***

## ***'How to Take a Drug into Humans for the First Time'***

### Monday

- 09.00 - 09.30: Registration and Coffee
- 09.30 - 09.45: Introduction
- 09.45 - 10.00: EMA and FIH Assessment Documents
- 10.00 - 10.45: First in Man Scenario
- 10.45 - 11.00: Coffee Break and General Discussion
- 11.00 - 11.30: An Overview of Drug Development
- 11.30 - 12.00: Investigational Medicinal Products
- 12.00 - 12.45: A History of Ethics
- 12.45 - 13.30: Lunch
- 13.30 - 14.15: Drug Regulations
- 14.15 - 15.00: MHRA and Governing Bodies
- 15.00 - 15.30: Coffee Break and General Discussion
- 15.30 - 16.00: Summary and Introduction to Tuesday

### Tuesday

- 09.00 - 11.00: Split Session - Preclinical Pharmacology
- 11.00 - 11.30: Coffee Break and General Discussion
- 11.30 - 13.00: Split Session - Preclinical Toxicology
- 13.00 - 14.00: Lunch
- 14.00 - 14.45: Pharmacokinetics
- 14.45 - 15.15: Pharmacodynamics
- 15.15 - 15.45: Coffee Break and General Discussion
- 15.45 - 16.15: Summary and Introduction to Wednesday

18.30 - 23.00: Informal Dinner and Networking (The Sheep's Heid)

### Wednesday

- 09.30 - 10.00: Statistics and Data Management
- 10.00 - 10.45: Dose Escalation Calculations
- 10.45 - 11.15: Coffee Break and General Discussion
- 11.15 - 12.00: Risk Assessment
- 12.00 - 12.45: Risk Management
- 12.45 - 13.45: Lunch
- 13.45 - 15.30: Risk Assessment Workshop
- 15.30 - 16.00: Coffee Break and General Discussion
- 16.00 - 16.30: Summary and Introduction to Thursday

## Thursday

09.00 - 11.00: Study Management

11.00 - 11.30: Coffee Break and General Discussion

11.30 - 13.00: Split Session - Adverse Events and Reporting

13.00 - 14.00: Lunch

14.00 - 15.30: Split Session - TGN1412 - case study

15.30 - 16.00: Coffee Break and General Discussion

16.00 - 16.30: Summary and Introduction to Friday

## Friday

09.00 - 11.00: Protocol Development Workshop

11.00 - 11.30: Coffee Break and General Discussion

11.30 - 12.15: Healthcare Market Place

12.15 - 13.00: Special Issues for Biologics

13.00 - 14.00: Summary and Closing Remarks