

## **The London experience - The TGN 1412 Trial**

### ***Introduction by Peter Dwyer, an Honorary Life Member***

*Peter Dwyer, who originally qualified in Pharmacy, was admitted to the Bar in 1978. He was the legal officer for the AMA (NSW) from 1979-1981. His practice includes a wide range of health-related areas. Since 1984, he has been a legal member of the St Vincent's Hospital Human Research Ethics Committee and the Scientific Conduct Committee. He is an Adjunct Associate Professor (Law and Ethics) in the Post-graduate Studies Program in Pharmaceutical Medicine & Drug Development, conducted by the Faculty of Medicine at the University of New South Wales, which includes legal and ethical aspects of clinical trials. He is currently Vice-President of the Australian Academy of Forensic Sciences.*

Some may wonder what 'The London experience' might be about. You could have very many experiences in London, but tonight's topic addresses the serious adverse events following the 'first-in-man' clinical trial in March 2006 of an experimental medication known as TGN1412.

This is a monoclonal antibody being developed as a treatment for leukaemia and autoimmune diseases such as rheumatoid arthritis. The adverse consequences caused a tremendous focus throughout the world upon human research experimentation, on clinical trials in particular, and as a subsection of that, on the place of the ethical approval of studies, particularly in healthy volunteers, on the interests of the subjects of research and of the community, and called attention to many issues: medical, legal, scientific and so on.

Tonight the Society is privileged to hear from Professor Tony Cunningham and Dr Arthur Rallis.