



# **An Overview of the Toxicology SIG**

**Mike Aylott  
GlaxoSmithKline**

28<sup>th</sup> September 2010

# What is the Toxicology SIG?



- A subgroup within PSI (Statisticians in the Pharmaceutical Industry)
- Currently one of the seven SIGs within PSI
- Five members of the Steering Team, from the main Toxicology sites in the UK (GSK, AstraZeneca, Pfizer, Covance, Huntingdon Life Sciences)
- Our list of ‘affiliates’ has grown to 40
- Our main aim is to promote best statistical practice in this area.

# History of the Toxicology SIG



- Founded in September 2006
- Ran our first workshop in September 2007 in the UK
- Repeated the workshop 12 months later
- Organised two sessions at the PSI/EFSPi Conference in May 2008
- Organised a third workshop in March 2010...



# Our Mission Statement



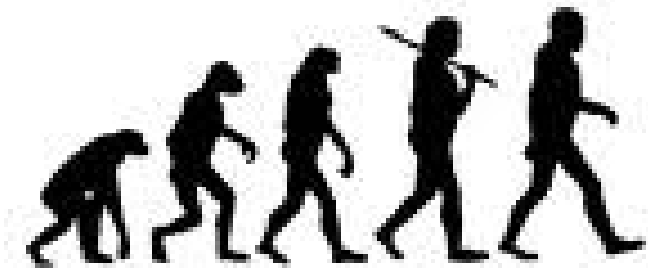
*To provide a forum to discuss the statistical issues involved in Regulatory and Investigative Toxicology.*

*Our membership consists of statisticians at CROs, pharmaceutical companies and academia who are working in preclinical areas such as:*

Acute Toxicology	Genetic Toxicology
General Toxicology	Immunotoxicology
Toxicokinetics	Toxicogenomics
DMPK	Histopathology
ECG	Safety Pharmacology

# Life Before the Toxicology SIG

- We all had the feeling of isolation, experienced by many statisticians in Toxicology!
- We would all develop our own solutions to a particular problem, by reinventing the wheel
- We had nobody to bounce our ideas against, or sharing of information in general.



# Methods Matrix

- This keeps an up-to-date record of all standard statistical analyses run by all sites for:-
  - **Micronucleus Test**
  - Organ Weights
  - **Cardiovascular Telemetry**
  - Ames
  - Carcinogenicity
  - CNS FOB/Irwin
  - **Comet.**

	Orientation			Translation
x-axis	scaleX	0	0	$t_x$
y-axis	0	scaleY	0	$t_y$
z-axis	0	0	scaleZ	$t_z$

# Dog Telemetry Analysis

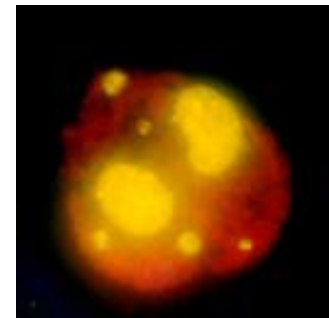


- The best practice for analysis of **Dog Telemetry** data was discussed at length during our 2008 Workshop
- We wrote a position paper on this, based on our discussions, covering a wide range of aspects
- This was submitted to the Pharmaceutical Statistics journal, and accepted in May 2010.



# Micronucleus Test

- The 2008 Workshop also contained discussions on the analysis of the **Micronucleus Test** (in Genetic Toxicology)
- In January 2009 we held a WebEx seminar, open to all Toxicology SIG affiliates, to summarise our findings
- A number of general conclusions were agreed upon for future analyses.



# Comet Analysis



- The analysis of the **Comet assay** was discussed in our 2010 workshop, and we have had three subsequent discussions
- We are looking to team up with JaCVAM (Japanese Center for the Validation of Alternative Methods) – the industry-wide initiative to look into the Comet analysis
- We are considering discussing this at the EMA/ISBS/IBS-DR conference in Berlin in March 2011.

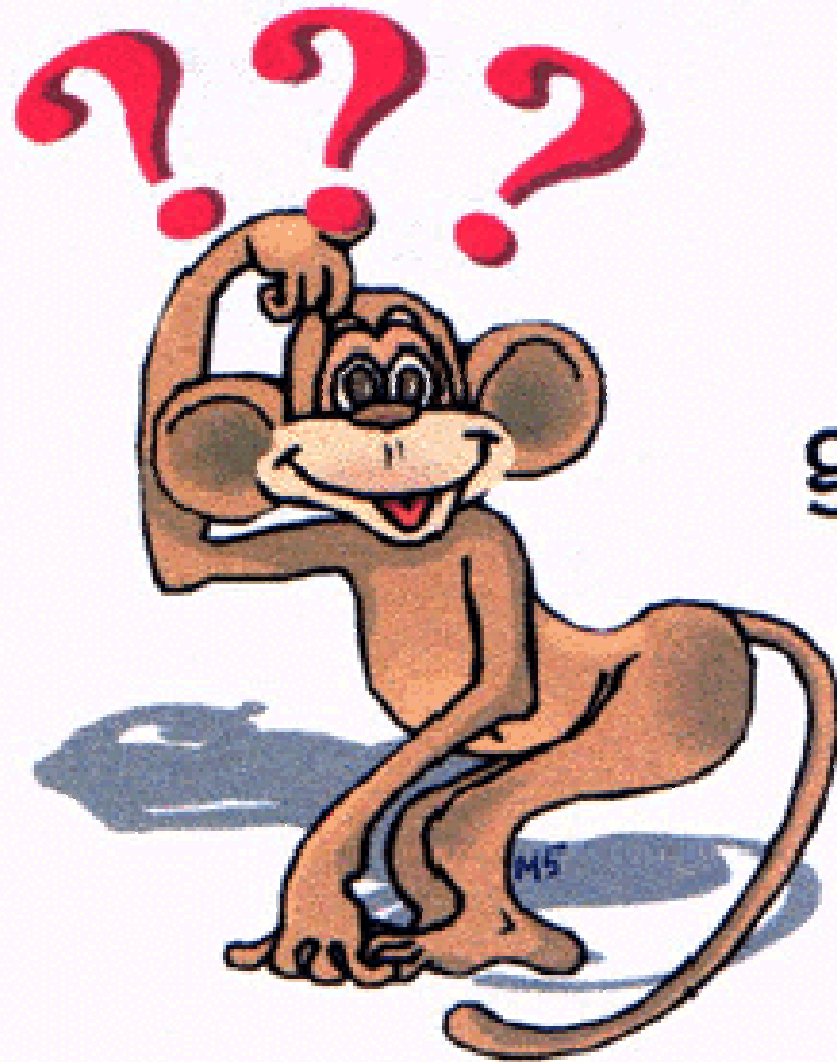
# The Future

- Our aim is to promote best statistical practice, and widen our influence, in as many areas of Toxicology as possible
- We aim to run a face-to-face workshop every 12-18 months
- We are convinced that there are sufficient “hot topics” out there to keep us in business!



# New Members Wanted!

- If you work in this area, and feel you can contribute, or would like to join our list of affiliates, please contact us!
- Check out our website:-
  - <http://www.psiweb.org/>
  - Committees and SIGs
  - Toxicology SIG.



Questions  
are  
guaranteed in  
life;  
Answers  
aren't.