

Reports from the 6th International Workshop on Genotoxicity Testing (IWGT)

**David Kirkland, UK, and Hans-Joerg Martus, Switzerland
IWGT 2013 Co-Chairs**

Thursday, 7th of November, 2013

IWGT



IWGT Steering Committee and history

David Kirkland (Co-Chair)	Consultant, UK
Hans-Joerg Martus (Co-Chair)	Novartis Institutes for Biomedical Research, Switzerland
Bhaskar Gollapudi	Exponent Inc., USA
Makoto Hayashi	BioSafety Research Center, Japan
David Jacobson-Kram	FDA, USA
Peter Kasper	BfArM, Germany
Lutz Müller	F. Hoffmann-La Roche, Switzerland
Yoshifumi Uno	Mitsubishi-Tanabe Pharma, Japan

- 5 previous workshops: Melbourne, 1993; Washington, 1999; Plymouth, 2002; San Francisco, 2005; Basel, 2009
- Consensus recommendations from these have been highly influential in shaping the revisions to OECD guidelines and the recommendations in the ICH S2 guidance.



IWGT Principles and Objectives

- To reach consensus recommendations on difficult or conflicting approaches to genotoxicity testing
- Consensus driven by data, taking all views into consideration, but in a spirit of compromise (where possible), or defining new areas of research and data-gathering if consensus cannot be reached
- Majority decisions can be accepted if objections (and limitations to consensus) are recorded



Working Practices

- Chairperson, Co-Chair, Rapporteur + invited experts (around the table and on-line/teleconference)
- Co-Chair of each group assist Chair to ensure all views are aired and to drive towards consensus
- Rapporteur captures consensus statements (and revises them) as they are developed, and project them on screen for all invited experts to read, digest, and comment
- Take questions from audience as time allows
- Agreed-upon statements form the basis of published reports which will appear in Mutation Research



2013 IWGT

Groups and their Chairs/Co-Chairs/Rapporteurs

- Liver micronucleus – Yoshifumi Uno, Takeshi Morita, Mirjam Luijten
- Pig-A – Bhaskar Gollapudi, Anthony Lynch, Bob Heflich
- Comet assay – Günter Speit, Hajime Kojima, Dan Levy

- Germ cells – George Douglas, Carole Yauk, Jan van Benthem
- Quantitative analysis – Jim MacGregor, Roland Froetschl, Paul White

- Panel Discussion: Next generation testing strategies – Kerry Dearfield, Bhaskar Gollapudi & Mirjam Luijten



Next steps after Brazil meeting

- Finalize consensus formulations and iron out details
 - Clearly identify areas of dissensus and open point where additional experimental work is needed
 - Prepare manuscript (end March 2014)
- Manuscript to be submitted by mid 2014 (Special Issue of Mutation Research)
- Slides of today's presentations will be made available via the IAEMS website: <http://www.icembrazil.org/icem/satellitesworkshops>
 - NB: Definitive recommendations of the working groups will be those published in Mutation Research



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