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 Steering Committee and history

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