

INTEGRATED TESTING STRATEGIES WORKSHOP

Brussels, 26 September 2011

flash



A FRUITFUL COLLABORATION BETWEEN REGULATORS AND THE REGULATED

In line with its 2011 theme, the European Partnership for Alternative Approaches to Animal Testing (EPAA) organised a workshop on Integrated Testing Strategies (ITS) on 26th September in Brussels. A well attended event gathering some 40 experts from regulators, industry and academia, this cross-sector workshop focused on what regulators and industry expect from ITS before they can be applied and impact Replacement, Reduction and Refinement of Animal Testing. The workshop, moderated by Gianni Dal Negro¹ and Joachim Kreysa² presented a unique opportunity for a two ways dialogue, first between «regulators» and the «regulated», and second across various sectors of industry.

The participants benefited from a comprehensive overview of what are the main issues at stake according to regulators. Representatives from ECHA, EFSA and EMA emphasized the scope for ITS in EU Legislation and the commitment of the regulators in favor of ITS.. More than in other sectors, ITS are used by industry and regulators routinely for regulatory testing of pharmaceuticals in Weight of Evidence risk assessments. Although there are possibilities for multiple and flexible approaches using individual 3Rs methods, there is still need for a defined process for regulatory acceptance of 3Rs, including ITS. Presentations from the industry members of EPAA provided the audience with a cross-sector perspective of the modern and more comprehensive decision-making processes allowed by ITS in the chemical, pharmaceutical and cosmetic fields. Concluding the industry session on ITS, G. Dal Negro stressed the active commitment of the industry in developing ITS that are relevant to human safety and cost

1 Dr Gianni Dal Negro is the current co-chair of the EPAA Steering Committee, and also represents GlaxoSmithKline as a DVM Toxicologist and Worldwide Director 3Rs in Animal Testing.

2 Dr Joachim Kreysa is an active member of the EPAA Steering Committee. He is also heading the In-vitro Unit at ECVAM, DG JRC, European Commission.

effective. He also highlighted the usefulness of coordination in recently emerging Public-Private Partnerships (PPPs) like the EPAA to advance the 3Rs development and acceptance with involvement of regulators.

The essence of the debate on ITS seems however to be the fact that, although regulatory schemes allow for the Implementation of ITS, clarity on the scientific decision-making process and regulatory acceptance of the decisions generated under ITS still needs further improvement.

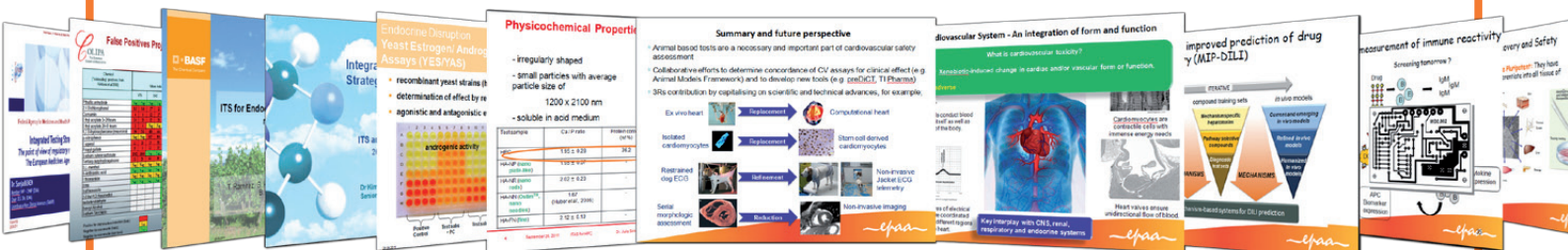


WHAT MAKES A GOOD ITS ?

Industry end users demand that ITS provide innovative scientific solutions and results in 3Rs wins.

In addition to 3Rs considerations, better prediction of human risk and major advancements in biology and computational modelling capabilities are the drivers for the recent paradigm shift from a traditional pathology-based toxicology to a pathway-based risk assessment.

Against this background, the workshop identified a number of criteria that ITS should meet if data generated are to be accepted in regulatory compliance procedures. A recurring issue was whether acceptance of data should be based on validated methods, or valid methods, meeting criteria such as scientific validity and robustness of method and endpoints, standardisation of assays and cell preparations, reproducibility of the results, endpoints/parameters relevant for assessment of human risk. Other aspects mentioned include the ability to allow risk assessment decisions where individual tests fail, coverage of all relevant non testing methods, a well defined applicability domain, consis-



tency, transparency and reproducibility.

Particular attention was given to the question how ITS could be further promoted. Suggestions were made to better integrate efforts in the different EU PPPs, bring advisory committees from different consortia together, co-ordinate with other publically-funded research within the EU, quantify 3R wins and communicate with the public and other stakeholders. Regulators suggested a number of general or more specific points of attention, including applicability, predictivity, extrapolation to humans, definition of health based triggers, assessing exposure-based waiving and non-testing data.

The workshop attendees acknowledged that implementation at regional level of new 3Rs methods including ITS is sometimes challenging, and they recommended international cooperation as a way forward.

Overall, workshop participants backed the need for ITS to provide more data than existing methods and agreed that "Industry, academia and regulators need to educate each other and ITS are among the most efficient solutions to address 3Rs"³. It was recommended that in a follow up meeting EPAA could bring together regulators from different EU agencies, ECVAM, OECD and industry to build consensus that would definitely help shape the future of ITS.

A complete de-briefing of the workshop will be presented at the EPAA Annual Conference on 9th November. Registration is available online. The workshop present-

tations and the full report will be made available on the EPAA [website](#) soon.



³ Quoting Dr Ian Cotgreave, lecturer at the Swedish Karolinska Institute who gave the workshop keynote on the State of Play of ITS.

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