

# STEM CELLS FORUM

flash



The European Partnership  
for Alternative Approaches to Animal Testing

London, UK, April 25<sup>th</sup> 2013

## New Perspectives on Safety Project - Stem Cells

>>> An event organized by the EPAA Stem Cells workgroup #3 -Communication

The EPAA Stem Cells Forum was hosted in London by the NC3Rs (National Centre for the Replacement, Refinement and Reduction of Animals in Research) on April 25th 2013. This event gathered 15 experts from industry, regulators and academia from all Europe and beyond.

The Communication workgroup of the EPAA New Perspectives on Safety-Stem Cells project, organized this Forum as part of the gap analysis strategy initiated two years ago in Ispra.

One of the aims of this Forum was to facilitate dialogue between stem cells stakeholders in order to build synergies and allow pooling of resources on stem cells research. Being facilitated by EPAA, this Forum had non-commercial purposes and was intended to share experiences, good practices and advice on stem cells research and to decide if the establishment of a permanent forum could help speed up the adoption of stem cells in future toxicological testing strategies.

The experts gave their input during two consecutive sessions on first, an overview providing participants with presentations describing the current state-of-the-art in their particular labs and/or consortia and second, a brainstorming session to identify gaps and define deliverables and next steps for the group.

### A COMPREHENSIVE OVERVIEW ON STEM CELLS RESEARCH

While the stem cells project has become one of the flagship initiatives of EPAA, much remains to be done

on communication between the large number of projects that are exploring current and future opportunities of stem cells in drug/chemical screening and regulatory testing, since research agendas and priorities are quite different from each other. EMA, the ESNATS Consortium and other relevant experts (see full participating organizations list below) raised the need for a cross-sector communication platform on stem cells in Europe that would complement the activities of the large deep-research consortia like ESNATS.

Presentations showed that both human embryonic stem cells and induced pluripotent stem cells are being studied by regulators, academia, and industry (including SMEs). Selected slides from the overview presentations will soon be available on the EPAA website.

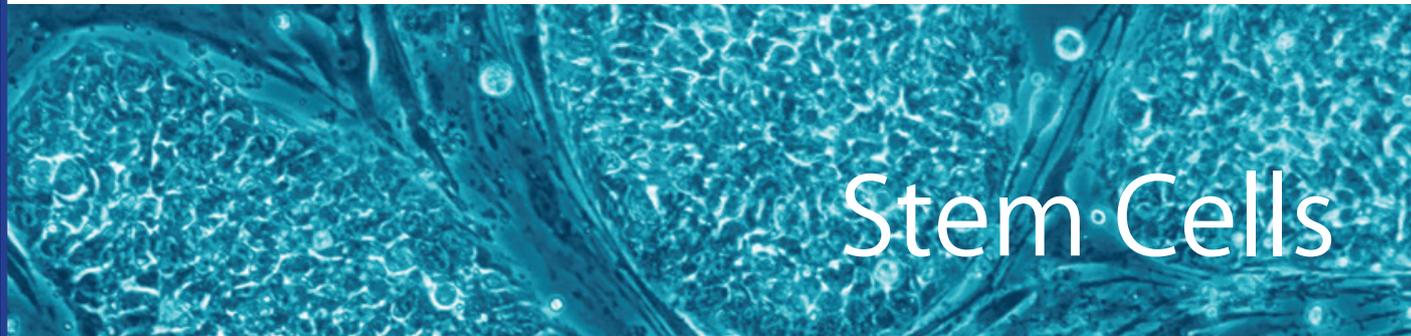
### EMERGENCE OF A NEW STAKEHOLDER: THE STEM CELLS IN SAFETY TESTING FORUM

The participants acknowledged that Europe has a head start over some other continents on alternative methods linked to stem cells. Non-European regulators might indeed be more reluctant to address validation needs of stem cell based test, giving the opportunity to Europe to develop more research on stem cell alternatives...

However, international collaboration should be promoted, as reminded by the EPAA lead theme for 2013 – 'International Cooperation on 3Rs'. International experts and regulators are therefore welcome to join the consortium. During the dialogue session, the consortium called for a reinforced collaboration through a dedicated platform, making clear that there is a need

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**“The group decided to establish a permanent not-for profit Forum for a more efficient research on Stem cells alternatives”**



Stem Cells

for an "established stakeholder" on stem cells (i.e. more than a simple think tank). The consortium agreed to focus on safety testing instead of the more generic "toxicology" and therefore called for the creation of a permanent "Stem Cells in Safety Testing Forum".

5 key issues have been identified for the Forum as priorities:

- importance of standardization of assay protocols,
- choice of test compounds,
- importance of maturity of cell phenotype,
- defining criteria for validation and acceptance of novel models,
- epigenetics.

The mandate of this non-commercial (international?) Forum is to provide a platform for permanent dialogue

between research groups, to share experiences, problems, successes and opportunities. Working together, forum members will be able to bring the full weight of their expertise to identify common problems and potential solutions appropriate for the wider community. Such collaboration would ideally start with a web-based tool allowing participants to share compounds, list priorities and identify possible synergies with other existing international consortia on stem cells.

Then, as a second step a workshop will be organized before the end of 2013 to write a position paper on the harmonization of stem cell work and safety assessment. A core group will soon organize this workshop (on invitation only) and include relevant pharmacologist stakeholders to have an optimal representation of experts on stem cells.

## Participating Organisations

- AbbVie, USA
- EMA, The European Medicines Agency
- EPAA, the European Partnership for Alternative Approaches to animal testing, Belgium
- ESNATS, Embryonic Stem Cell-based novel alternative testing Strategies
- European Commission DG JRC - EURL ECVAM, The European Union Reference Laboratory for Alternatives to animal testing
- University of Lisbon, IMED (Reserach Institute for Medicines and Pharmaceutical Sciences), Portugal
- IMI MIP-DILI, Innovative Medicines Initiative- Mechanism based Improved Prediction of Drug-Induced Liver Injury, Belgium
- INSERM, Institut National de la Santé et de la Recherche Médicale, France
- NC3Rs, National Centre for Replacement, Refinement and Reduction of Animal Testing, UK
- SC4SM, Stem Cells for Safer medicines, UK
- SCR&Tox Consortium
- StemBanCC, Stem Cells for Drug Discovery, Germany
- University of Applied Sciences and Art Northwestern Switzerland (FHNW), Switzerland

## About EPAA

EPAA is a Public-Private Partnership across seven industry sectors and between European Commission and Industry stakeholders. Launched in 2005, it gathers 36 companies, 7 European trade federations and 5 Directorates-General of the European Commission.

Further information is available on [www.epaa.eu.com](http://www.epaa.eu.com)

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