

Scientific plans, new calls, status of projects & proposals for the 7th EU FP

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- ❖ Meeting 0. Identifying bottlenecks in drug development: how can alternatives help?
- ❖ Meeting 1 Reduction
- ❖ Meeting 2 Refinement
- ❖ Meeting 3 Replacement

ForInvitox

- Signed the 28 June 2007 and according to the contract it enters in to force this date. The duration of the contract is 24 months.
- 4th October 2007 kick-off meeting in Elche (Spain)

Partners:

- Expertadret, Cecila Clemedson Coord.
- REMA, Eugenio Vilanova
- SET, Christianne Buta
- IVTIP, Joan Albert Vericar
- SILVERDAL **Science Park**, Erika Toft
- ***Ecopa***, Odile de Silva

State of the art

WP1 - Retrieval of existing, not properly exploited knowledge

An in-depth review of the five *in vitro* testing projects funded by the EC under the 5FP, as well others existing knowledge (**deliverable**).

Work package leader: P2

Involved: P1-4

WP2 – The needs of *users*

Compilation of the end-users needs and demands for *in vitro* toxicity tests (**deliverable**).

Work package leader: P4

Involved: P1-4

WP3 - The availability of *producers*

A comprehensive inventory of *in vitro* test producers and their capabilities/limitations to meet demands (**deliverable**).

Work package leader: P1

Involved: P1-4

Identification of needs

WP4 – Analysis of data and Action Plan for a Forum

- Report summarizing the supply and demands for *in vitro* toxicity tests (**deliverable**).
- Identification of the most urgent testing needs and accordance between the developed *in vitro* toxicity tests and the industrial testing needs together with input from the highly qualified Expert Group (**deliverable**).
- Action plan with an analysis of the testing needs and the possibilities to meet the future demands for *in vitro* toxicity tests (**deliverable**).

Work package leader: P2

Involved: P1-4 and Silverdal Science Park (sub-contractor)

Strategies to meet future demands

WP5 – Forum-event

- Preparation of relevant questions for the discussions taken place at the Forum-event (**deliverable**).
- Establishment of a Forum with representatives from manufacturers of *in vitro* toxicity tests, research projects developing and validating alternative tests, regulatory agencies and end users. Arrangement of a Forum-event (**deliverable**).
- A continuous and interactive forum for discussion, information and education around issues concerning implementation and use of alternative toxicity tests, including presentations of innovations and manufacturers.

- The outcome from the Forum-event will be a *White book* recommending actions to meet the increased need for alternative toxicity tests (**deliverable**).

Work package leader: P5

Involved: P1-5

Other non-succesful initiatives:

“Long-term research strategy for the full replacement of animal tests for repeat dose systemic toxicity”.

Coordinated by Christa Hennes (18 April 2007)

Participants: R. Bars, J. Castell, B. Garthoff, I. Manou, C. van Laar, V. Rogiers (partly), C. Hennes

- The current concept note and additional project ideas are a good start but need substantial further discussion.
- The time left until the deadline of the FP7 call (May 2) is too short to prepare a solid project proposal.
- The group expressed interest to further develop the concept of a project towards a long-term research strategy on alternatives to current RDT testing.

1	Title:	<u>Novel <i>in vitro</i> testing platforms based on intra-and extracellular sensing</u>
	Project Acronym:	CELLSENS.
	Project Reference:	QLK3-CT-2001-00244
	Contract Type:	Cost-sharing contracts
	Start Date:	2001-11-01
	End Date:	2004-10-31
	Duration:	36 months
	Coordinator:	Dr. Tautgirdas Ruzgas, Lund University
2	Title:	<u><i>In Vitro</i> production of high quality mammalian oocytes for biotechnology, assisted reproductions, breeding and toxicology-teratology purposes.</u>
	Project Acronym:	EX OVO OMNIA
	Project Reference:	QLK3-CT-1999-00104
	Contract Type:	Cost-sharing contracts
	Start Date:	2000-02-01
	End Date:	2003-07-31
	Duration:	36 months
	Coordinator:	UNIVERSITE CATHOLIQUE DE LOUVAIN
3	Title:	<u>Human cell systems for predicting the allergenicity of genetically engineered proteins.</u>
	Project Acronym:	HUCCELLALL
	Contract Type:	Cost-sharing contracts
	Start Date:	2001-01-01
	End Date:	2003-12-31
	Duration:	36 months
	Coordinator:	DEPARTMENT OF IMMUNOTECHNOLOGY, LUND UNIVERSITY
4	Title:	<u>Comparison and validation of novel pyrogen tests based on the human fever reaction</u>
	Project Acronym:	HUMAN(E) PYROGEN TES
	Project Reference:	QLK3-CT-1999-00811
	Contract Type:	Cost-sharing contracts
	Start Date:	2000-02-01
	End Date:	2003-01-31
	Coordinator:	STEINBEIS TECHNOLOGY TRANSFER CENTER FOR IN-VITRO PHARMACOLOGY AND TOXICOLOGY. KONSTANZ
5	Title:	<u>Prevalidation of novel alternative pharma-/toxicological screening based on yeast expression technology</u>
	Project Acronym:	MULTIPLEX
	Project Reference:	QLK3-CT-2001-00401
	Contract Type:	Cost-sharing contracts
	Start Date:	2001-11-01
	End Date:	2005-04-30
	Coordinator:	RHEINISCHE FRIEDRICH-WILHELMS-UNIVERSITÄT BONN

ForInViTox - Forum for researchers and regulators to meet manufacturers of toxicology test methods. The purpose of the project is to establish a Forum where representatives of manufacturers, researchers, end-users and regulatory agencies continuously get a chance to discuss how to speed up the process of making *in vitro* methods available for end-users. The ultimate goal of the project is to increase the use of in vitro assays in toxicity testing.

Before the establishment of the Forum the following activities will take place within the project:

An analysis of the needs of toxicity tests among end-users.

An inventory of producers of *in vitro* toxicity tests.

A retrieval of existing, not properly exploited knowledge.

We are therefore interested in identifying:

Producers (kit producers and CRO:s performing in vitro toxicity testing) and end-users of in vitro toxicity assays in the European Countries. **We kindly ask you to help us to identify as many of these companies as possible.** We also would like to get contact information and if possible area of interest. Please, use the attached Excel table to fill in the asked information.

In vitro toxicity methods with potential to be further developed to commercial test assays. **We kindly ask you to give us information on methods, developed in your Country, which you think have potential to be used commercially for toxicity testing.**