



START-UP

Scientific and Technological Issues in
Alternatives Research in
Drug Development and Union Politics

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Chair of *ecopa*

**FP 7 PROJECT:
Scientific and technological issues in
3Rs alternatives research in the
process of drug development and
Union politics**

Coordinator *ecopa*



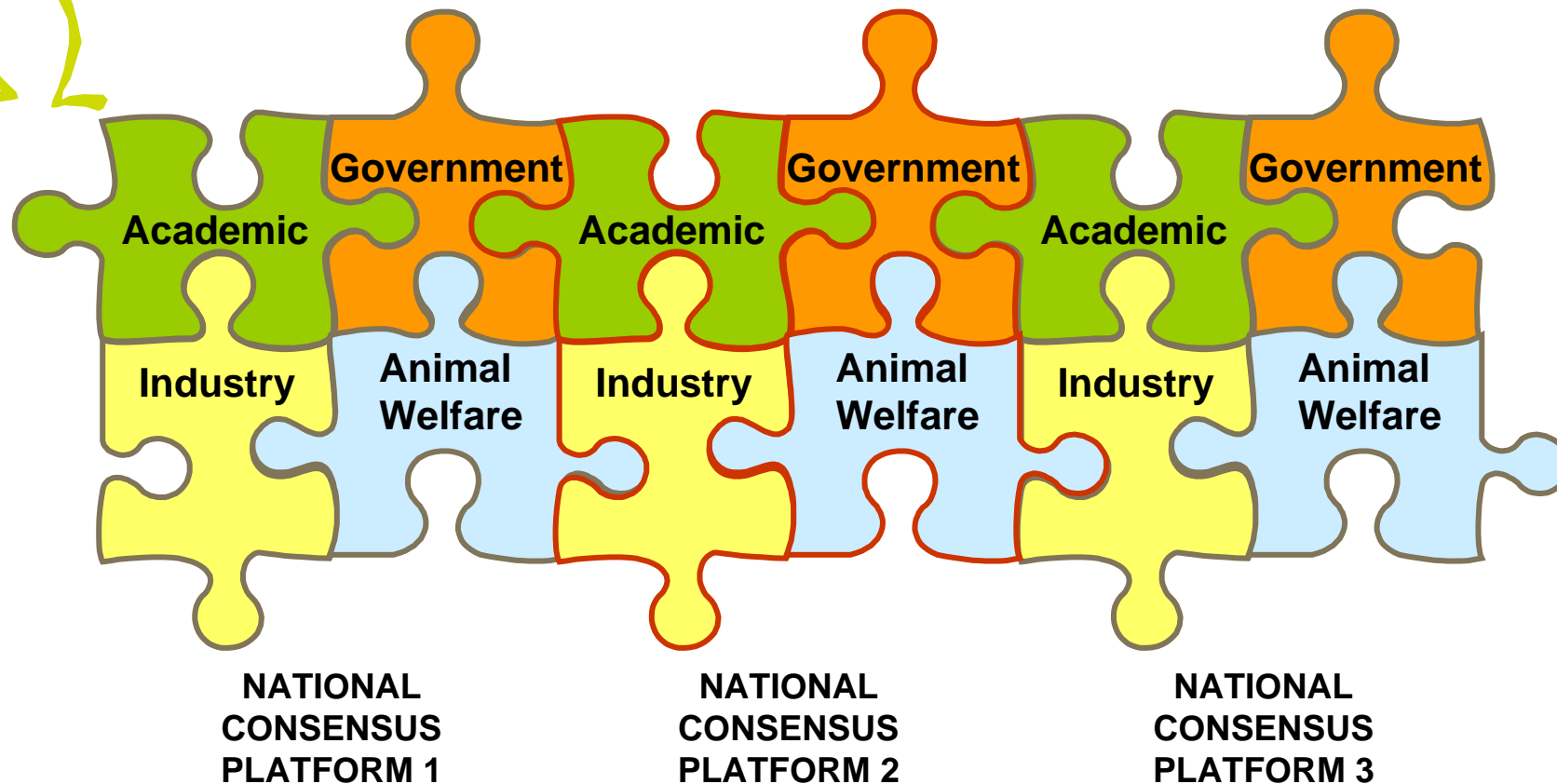
- **What is *ecopa*?**
- **What is the **START-UP** project ?**

What is *ecopa*?



European Consensus Platform on 3R-Alternatives.

***ecopa* is a quadripartite umbrella organisation at the European level**





What is ecopa?

GOALS: Promotion and development of 3R- Alternatives

ACTIVITIES:

- BUILDING NCP's

Actual Status: 13 full members (existing consensus platforms)

Austria, Belgium, Czech Republic, Denmark, Finland, Germany, Hungary, Italy, The Netherlands, Spain, Sweden, Switzerland (and United Kingdom)

3 associated members (consensus platform under formation)

Norway, Poland, France

Interested member

Ireland

What is *ecopa*?

ACTIVITIES:

- **SUPPORTING THE DEVELOPMENT OF 3R- ALTERNATIVES VIA 4 WG's**

RESEARCH
POLICY
EDUCATION
ETHICS

- **DISSEMINATION OF 3R-INFO**

- *ecopa* website: www.ecopa.eu

- *ecopa* messenger :



- **ORGANISATION OF YEARLY WORKSHOPS**

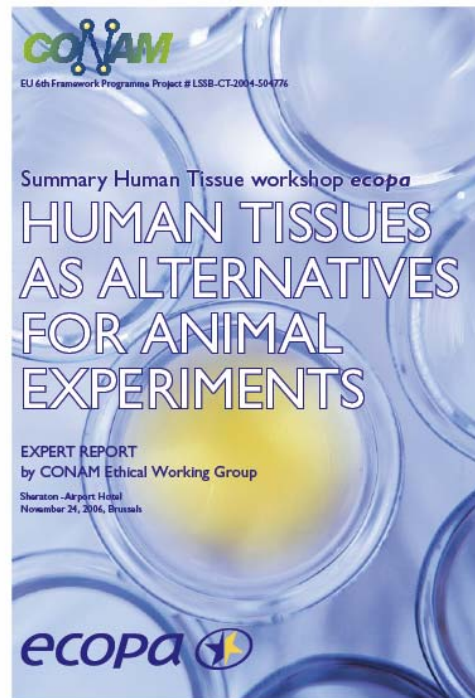
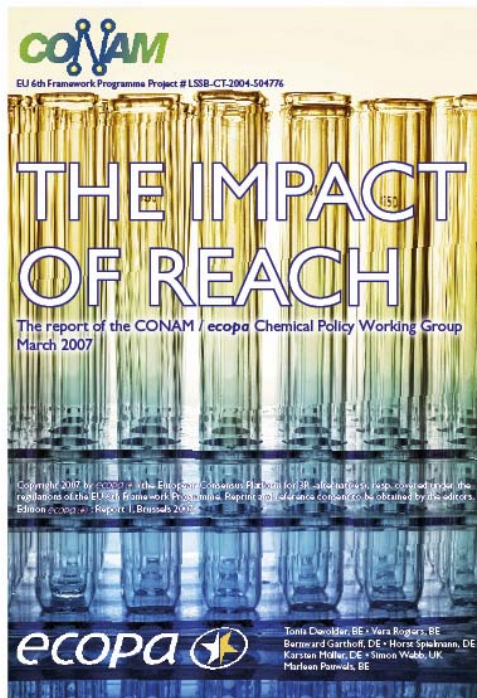


- **ORGANISATION OF 2 YEARLY eSI WORKSHOPS**

What is *ecopa*?

ACTIVITIES:

- **EXPERT REPORTS ON CRITICAL 3R- ISSUES**



What is ecopa?

ACTIVITIES:

- PARTNER FOR DISSEMINATION OF RESULTS OF EU PROJECTS ON 3R-ALTERNATIVES

- FP6 PROJECTS

Predictomics

ReProTect



Sens-it-iv



CarcinoGENOMICS



- FP7 PROJECTS

HERMES

Esnats

- Coordinator of EU PROJECTS

In FP6: CONAM



In FP7: START-UP



What is **START-UP**?



WHY FOCUS ON PHARMACEUTICAL DISCOVERY AND DEVELOPMENT?

COMPLEX PROCESS CONSISTING OF

- Target identification
- Target prioritization/ validation
- Lead identification
- Lead optimization



PROBLEM
TOO MANY FAILURES FOR SAFETY AND EFFICACY REASONS IN
LATE STAGE DEVELOPMENT



HIGH ANIMAL USE, HIGH COST, TIME CONSUMING AND COMPETITIVENESS ↓

What is **START-UP**?



WHY FOCUS ON PHARMACEUTICAL DISCOVERY AND DEVELOPMENT?

ADDITIONAL PROBLEM

EMERGING NEW DRUG CANDIDATES AND NEW TECHNOLOGIES

- biologicals
- monoclonal Abs
- high MW peptides
- proteins
- nanotechnological drugs



What is **START-UP**?



MORE MECHANISTICALLY BASED SAFETY AND EFFICACY TESTS



POSSIBILITY FOR USE OF 3R-ALTERNATIVE METHODS



SAVING ANIMALS, PROMOTION OF 3R-ALTERNATIVES USE

What is **START-UP**?

BUT **CRUCIAL** IS THE IDENTIFICATION OF THE BOTTLENECKS FOR THE USE OF 3R-ALTERNATIVES IN THE PHARMACEUTICAL INDUSTRY AT DIFFERENT LEVELS

- SCIENTIFIC
- TECHNOLOGICAL
- POLITICAL
- REGULATORY

What is **START-UP**?


SOME BOTTLENECKS EXAMPLES.....


LACK OF

- Metabolising systems or use of old fashion technology in actual alternative methods
- Well-defined application domains for currently available alternatives
- Functionality of primary cell cultures
- Crucial alternative methods for quantitative safety assessment such as repeated dose toxicity, developmental toxicity, systemic organ toxicity,.....
- Specific (bio) markers and endpoints
- Miniaturisation and engineering of existing alternatives
-

What is START-UP?

GOAL?

-  **The START-UP project is concerned with the identification and proposal to abolish bottlenecks in the 3Rs approach in pharmaceutical discovery and development.**

-  **The goal of the project is the organisation of 3 Workshops in order to determine**
 - a) the state of the art of each of the 3Rs in the EU,
 - b) to assess European strength and gaps in 3Rs and
 - c) the identification of rate limiting steps on the political, scientific, technological level.

What is START-UP?



Expected Results

A Consensus Paper containing the concepts and suggestions for a **Roadmap** for future research



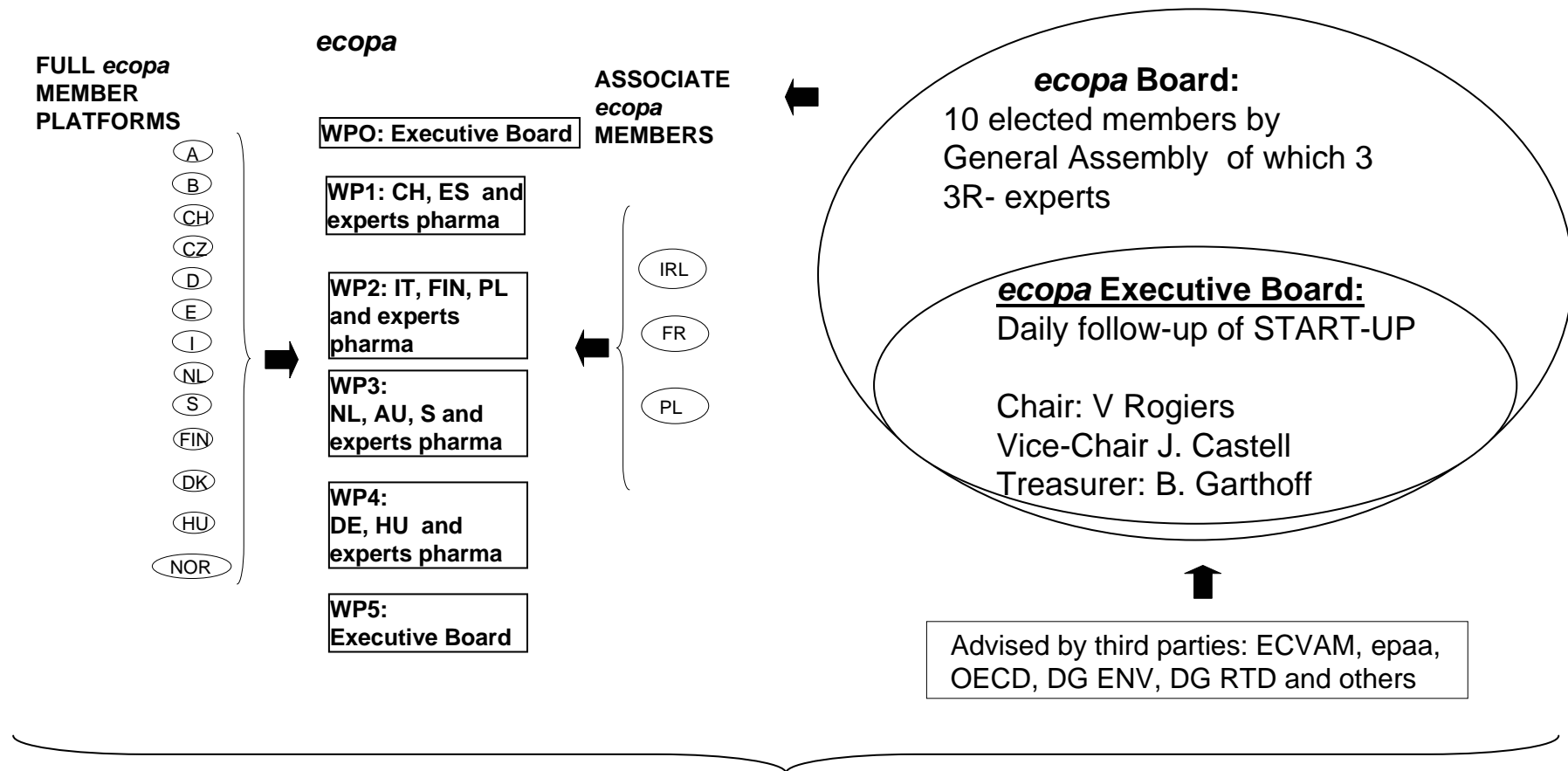
A **consensus document** that analyses the present status of the 3R alternatives and offers possible solutions.



Based thereon, a **Road Map** to implement the strategy for a better integration of 3Rs in the EU drug discovery and development strategy will be proposed.

What is START-UP?

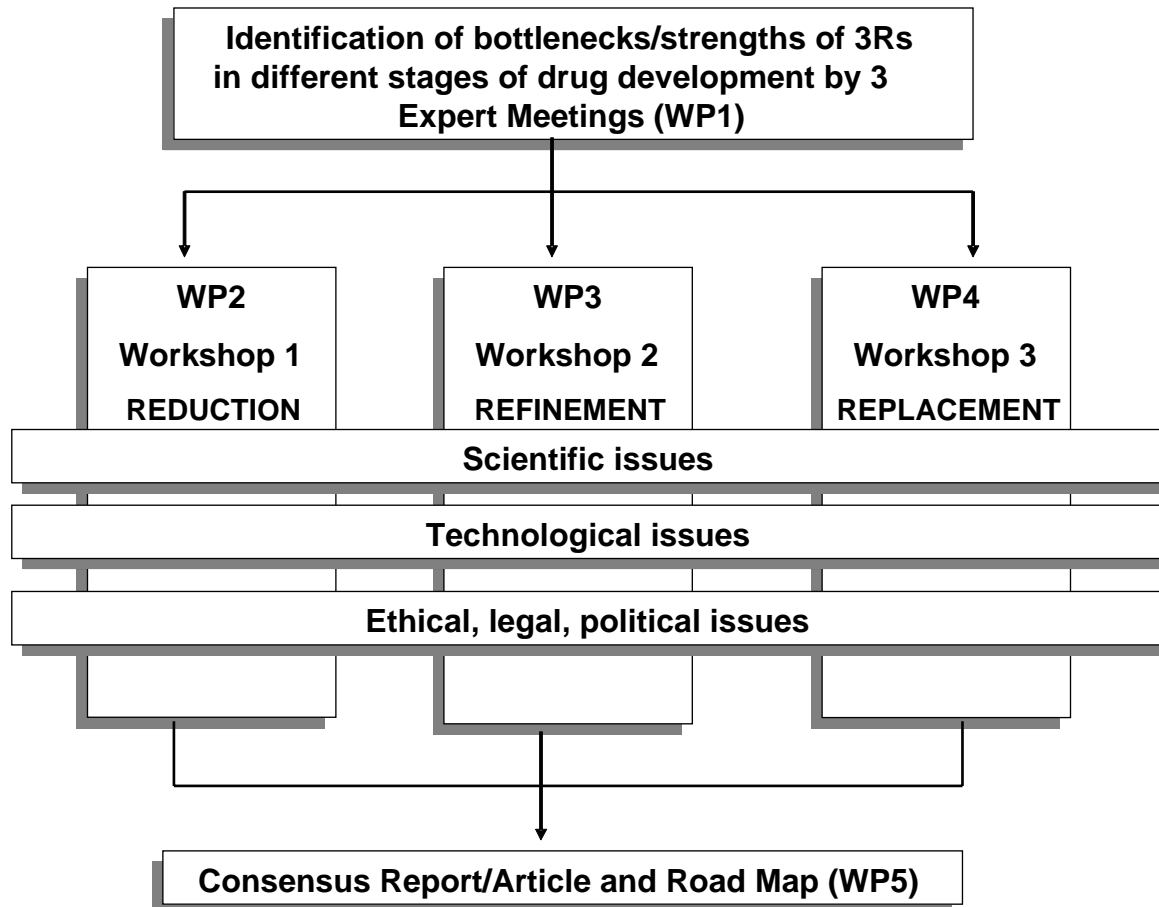
Proposal for the general organisation of START-UP project



Backed up by scientific/administrative ecopa secretariate

What is START-UP?

Overview of the proposed working plan



What is START-UP?

Proposed Work Packages

WP	Description	Major Role for
WP0	Management	
WP1	Redefinition of bottlenecks in 3Rs in pharmaceutical discovery and development: Meetings with pharmaceutical industry	Board
WP2	Bottlenecks/ strenghts in Refinement Organisation of workshop	NCPs
WP3	Bottlenecks/ strenghts in Reduction Organisation of workshop	NCPs
WP4	Bottlenecks/ strenghts in Replacement Organisation of workshop	NCPS
WP5	Consensus report, Scientific Paper and Roadmap	Board and NCPS

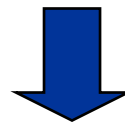
What is START-UP?

Need for additional Experts

- FIRST TASK OF WPs :

CONTACT WITH EXPERTS OF PHARMACEUTICAL AND/OR BIOTECH
INDUSTRY

EXPANSION OF EXPERTS LIST AND BALANCED COMPOSITION



PROPOSALS ARE
HIGHLY WELCOMED

BUDGET INVOLVED?



TOTAL OF 318,000€

Salary of full time (WP 1) scientific person for 2 years: coordination & practical support of meetings and workshops	128.000€
General Working (WP 0, 1, 5) (audit, consumables, travel, newsletter, website)	32.000€
Workshops (WP 2, 3, 4) (45.800€ per workshop)	137.500€
Indirect costs	20.500€
TOTAL	318.000€



NEGOTIATIONS ?

NEGOTIATIONS:

09.11.2007: SUBMISSION OF THE FINAL VERSION

15.11.2007: FINALISATION OF FIRST NEGOTIATIONS

TENTATIVE START DATE : 01/01/2008