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CarcinoGENOMICS: questionnaire and workshop in checking regulator's role

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Test method development: From R&D to Implementation

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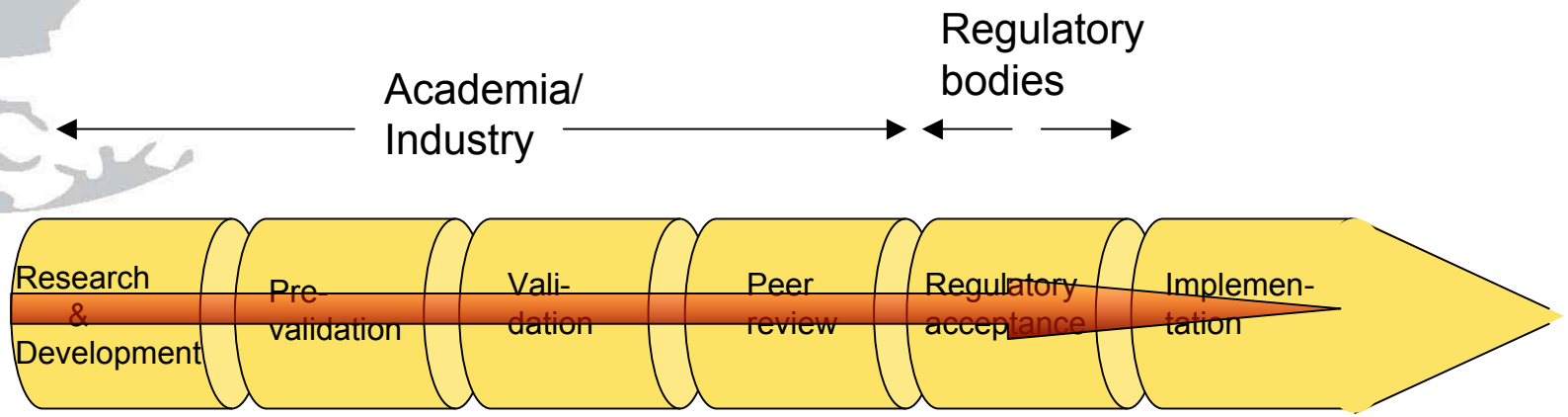

Test method development: From R&D to Implementation

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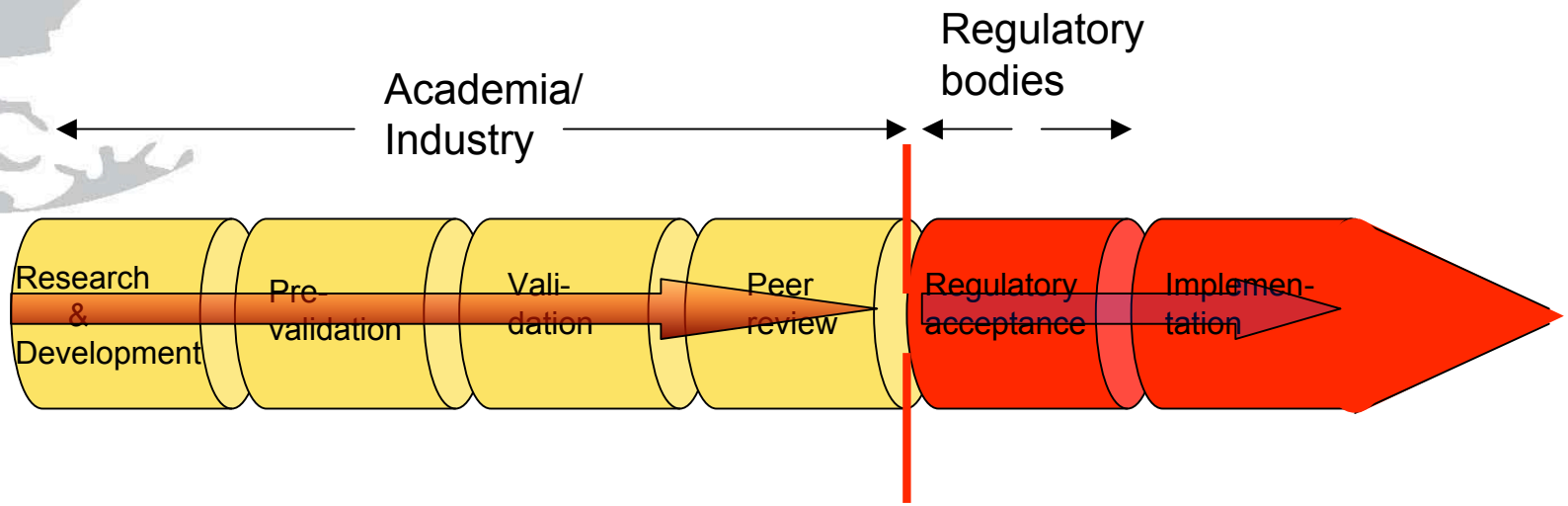

Lack of regulatory acceptance

Various reasons, such as

- No conclusive data
- Poor design validation study
- Application domain not well defined
- Etc.

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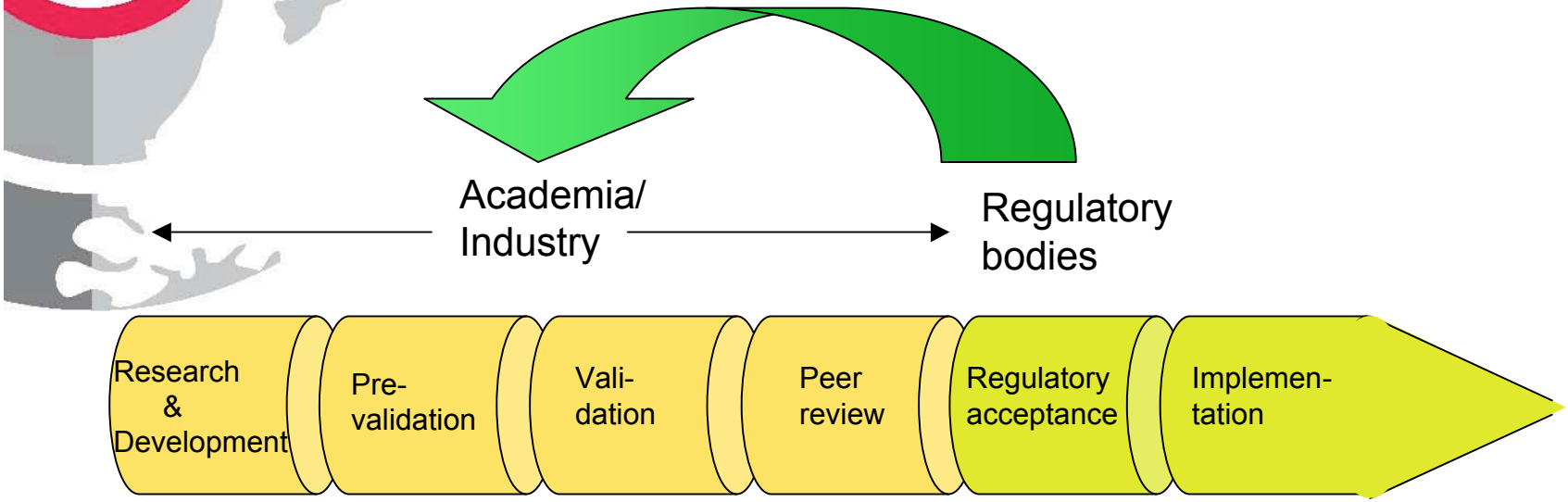

Statements at EPAA's 2007 Conference

Commissioner Potočnik: called for a systematic and sustained exchange between regulators, research community and industry

Commissioner Verheugen: stressed a greater involvement by authorities throughout the process from validation to acceptance

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Regulatory involvement

Objective for the regulatory input

- Focus on most promising methods (prioritisation on 3Rs needs, test needs, etc)
- Fine tuning validation to specific regulatory needs
- Speed up regulatory acceptance and implementation (e.g. engage regulatory bodies, efficient information structure, review whether regulatory needs are met)

(*S.Louhimies*)

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Major aim of FP6 carcinoGENOMICS project is to develop *in vitro* methods for assessing the carcinogenic potential of compounds, as an alternative to current bioassays for genetoxicity and carcinogenicity. The ultimate deliverable of the carcinoGENOMICS project wil be an optimised battery of organ specific, genomics-based *in vitro* assays, to be submitted to ECVAM to undergo formal validation

Workpackage 11.1 'Regulatory and legal feasibility': to define the data requirements needed for highly innovative test methods to become accepted in the regulatory process and to discuss the involvement of regulatory agencies in the route from test development to acceptance and beyond.

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Workpackage 11.1

Activities :

- Develop questionnaire and guidance document
- Organise workshop(s) with regulators & other stakeholders (industry & academia)

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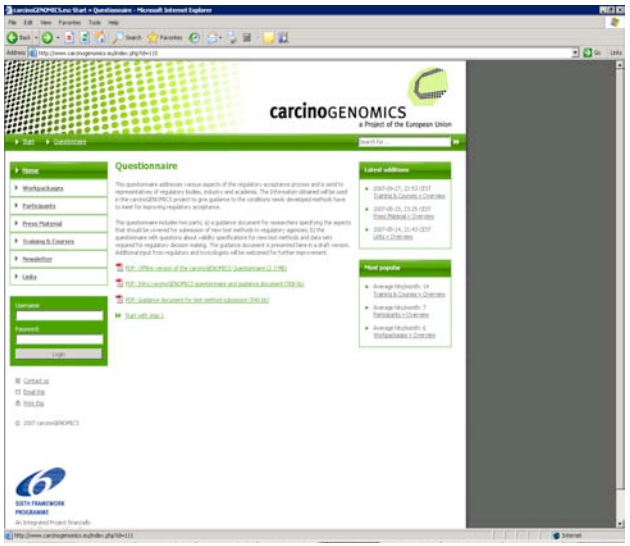
Questionnaire



The relevance of -omics data for risk assessment

(types of biomarkers, single genes vs expression profiles, kind of contribution, data needs)

Validation criteria

(innovative technologies, test purpose, criteria for acceptance, use of test monitoring systems, selection of chemicals/substances)

Technology transfer

(training needs, workshops, standardisation, GLP)

Involvement of regulatory bodies (**why**, **when** in process, **what** will be their involvement)

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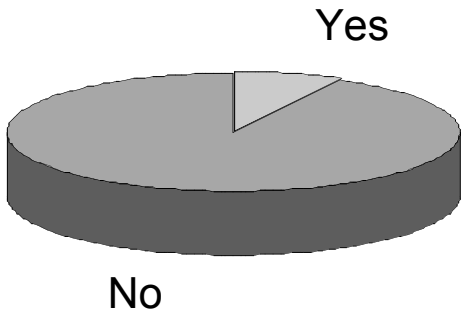
Questionnaire

No of responses: 17

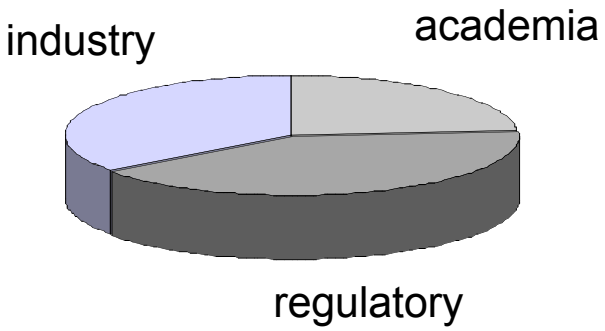
- 7 regulators
- 6 industrial toxicologists
- 4 respondents from academic setting

Total no.distributed: 204



Reasons for low response:

- Common problem of questionnaires
- Type of questions: time consuming
- Answering questions required specific expertise



Nevertheless: information provided of high quality

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Outcome questionnaire and workshop

Why should regulators be involved and **what** can they contribute?

Because they want to and we want them to be involved

- provide information on data needs for risk assessment
- give input to test design
- 'train' the developer in the regulatory process
- provide information on which criteria are essential for regulatory acceptance

When should regulators become involved?

During test development or in the pre-validation stage

What should be their involvement and **what** is needed?

As advisor to or member of the managing group

Information and training

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Questionnaire and workshop: some views and ideas

- Broad feeling that omics based methods are difficult to use for risk assessment (no quantitative dose-response information)
- Role of omics might be two-fold:
  * elucidating toxicological pathways and providing mechanistical understanding
  * as high throughput techniques for priority setting
- Opinions differed about validation needs for test modifications (innovative technologies)
- Need for information and training was stressed. Be a missionary!
- Quality of test development should be guaranteed but, apart from the formal validation study, not too much burocracy

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"Risk assessors need to be comfortable that scientists are working on things they can use"

(*Quotation from the workshop*)