

# **Resuscitating Cardiovascular Research in Europe post 1/5/04**

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# Cardiovascular Research in Europe

- **Why does it need Resuscitating ?**
  - Cardiovascular Research in Europe is strong
  - No room for complacency:
    - Research emphasis has shifted to laboratory-based sciences
    - Much less emphasis on Clinical, Patient-orientated research and population sciences
    - Fewer trainees in Clinical Academic Medicine

# Cardiovascular Research in Europe

- **Why “Post 1/5/04 ?”**
  - Introduction of the European Clinical Trials Directive (CTD)
  - To be implemented in all member States by May 2005

# Cardiovascular Research in Europe

- **Issues to be Addressed:**

- Impact of the European CTD
- Aspects of Research emphasis and assessment
- Fewer trainees in Clinical Academic posts
- Funding shortfall for research

# Cardiovascular Research in Europe

**What is  
“ the European Clinical  
Trials Directive” ?**

# The EU Clinical Trials Directive

- The objective of the Directive was to harmonise the clinical trials approval process across the EU.
- The EU CTD has broad and important implications for the way in which studies involving human subjects will be conducted in Europe.
- Ethical, legal and practical aspects of trials involving both patients and healthy volunteers, whether sponsored by academia, industry, research organisations, charities or government bodies, are affected.

# The EU Clinical Trials Directive

- The EU CTD is written on the implicit assumption that the purpose of performing a clinical trial is to produce data for a Marketing Authorisation application to a national or international regulatory authority.
- However, the Directive requires anyone who performs a clinical research study in the EU that involves the safety or efficacy of a medicinal product (even those clinically approved) to comply with its regulations – including pilot studies.

# EU CTD: A major Administrative and Financial Burden



# The EU Clinical Trials Directive

- The Directive imposes legal responsibilities on the trial sponsor (with the implicit assumption that it is a pharmaceutical company).
- For investigator-led/initiated research in academic institutions, this places an obligation on the sponsor for onerous administration, pharmacovigilance, adverse event reporting, archiving, GCP, drug packaging, site visits, etc.
- In the non-commercial sector the issue of who should be the sponsor is extremely contentious and many organisations are unprepared to accept this role.

# EU CTD: The "Sponsor Problem"



# The EU Clinical Trials Directive

## **EU clinical trials directive: 0% inspiration, 100% perspiration?**

The deadline for implementation of the European Union (EU) clinical trials directive passed on May 1. According to the European Commission, around half of

collectively. This apparently simple solution may sound good in theory but could prove difficult to negotiate in practice: some fear that the good

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## **Who's afraid of the European Clinical Trials Directive?**

Wouldn't it be nice if the approval and monitoring of clinical research done in the many, varied, and ever-increasing number of European countries could be

aspects of a trial but no one person or organisation is required to take overall responsibility. The inscription of this requirement into law will expose the single

# ESC Web questionnaire on EU CTD

- **Method:**

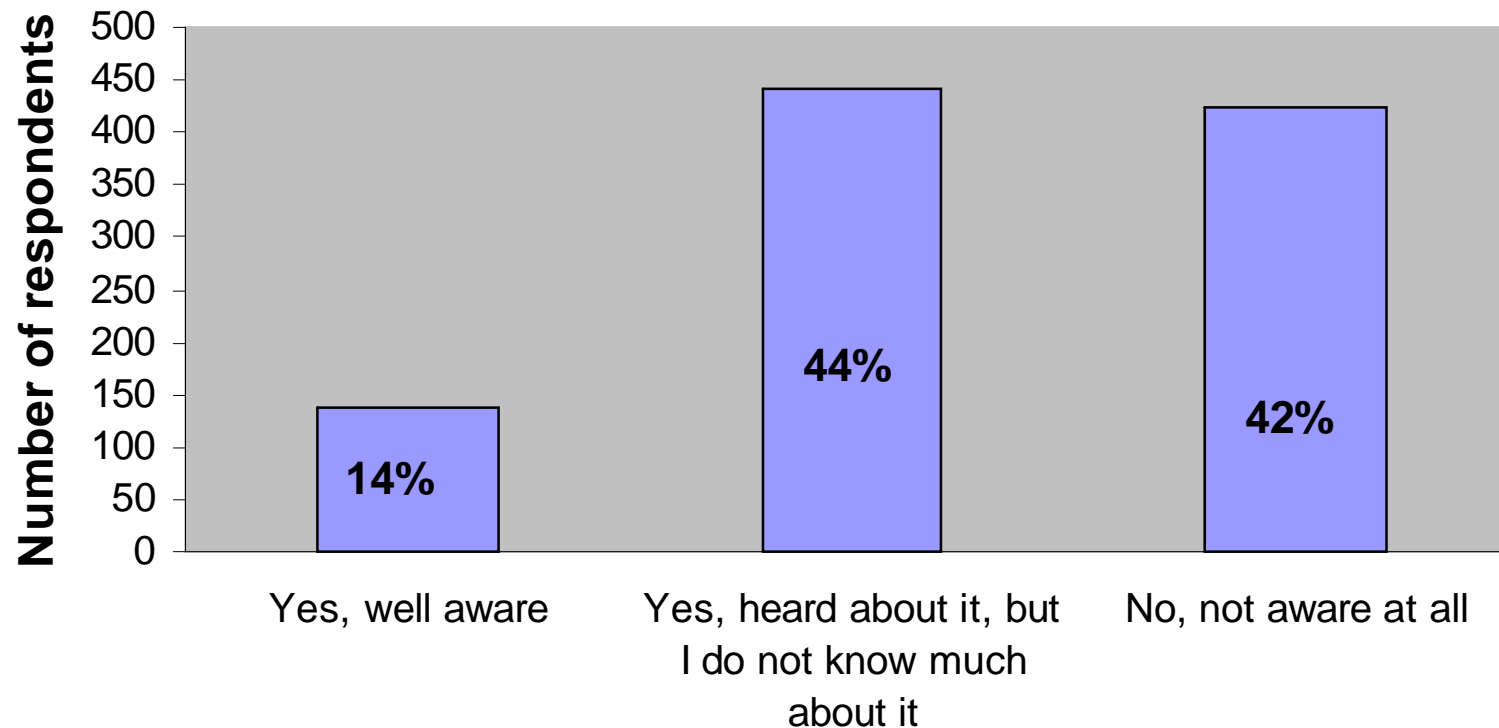
- targeted emailing of on-line questionnaire to 10,009 clinical researchers (abstract submitters to ESC Congresses, ESC Fellows (in the EU) and ESC Opinion leaders).
- 6 questions (approx. 4 mins to complete)

- **Results:**

- 1005 answers in 10 days

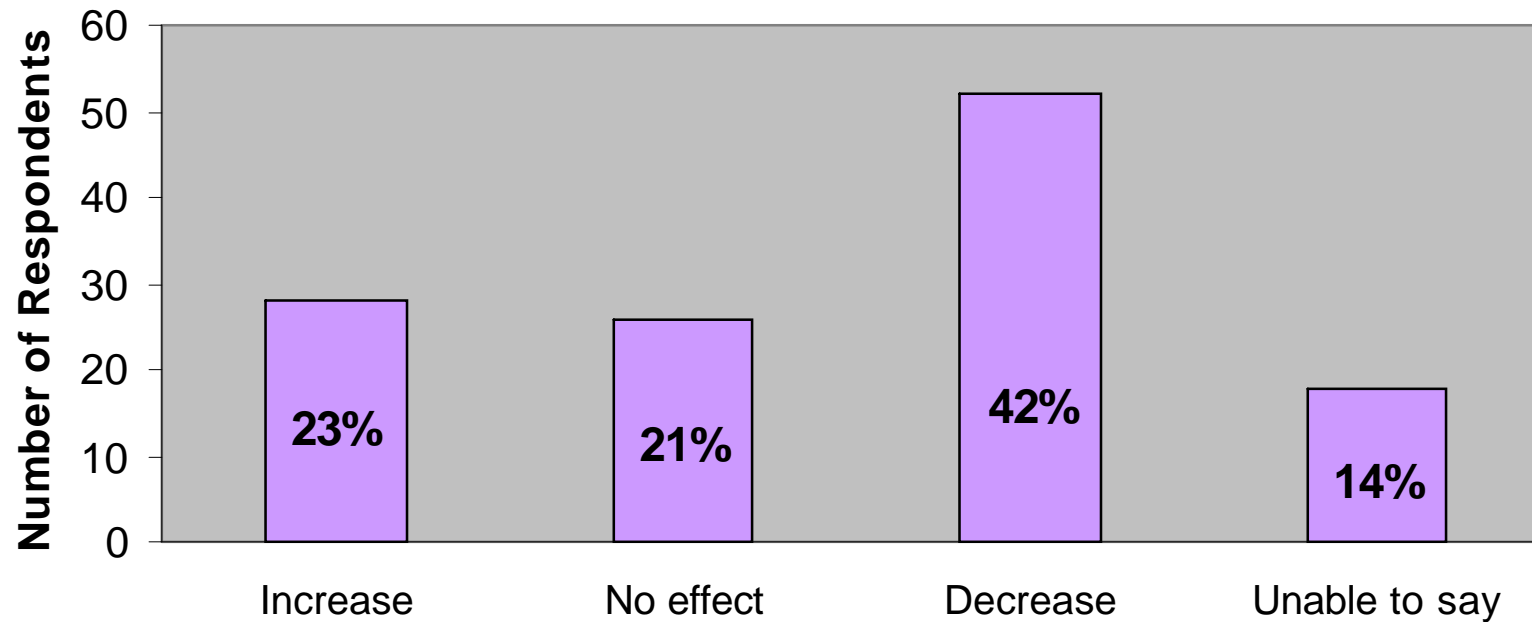
# Do you know the Directive?

Are you aware of the EU Clinical Trials Directive (Directive 2001/20/EC) that is determining Clinical Trial practises in Europe as from May 2004?



## Impact on number of studies

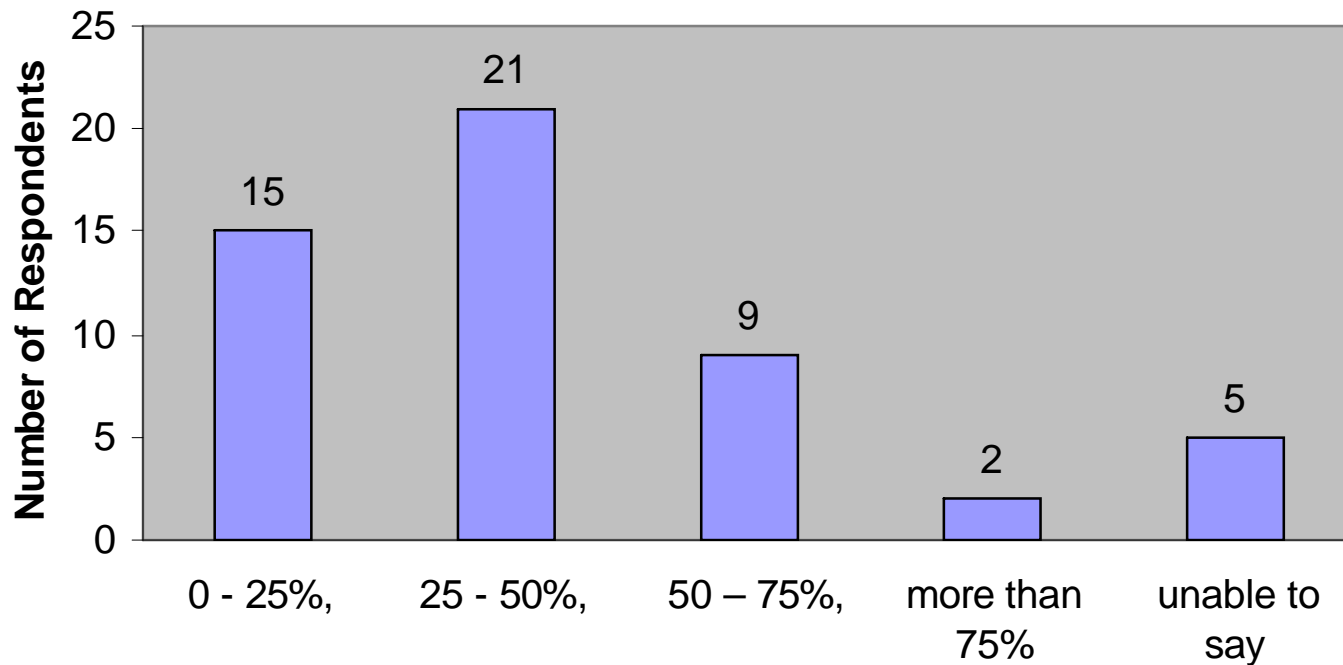
In your opinion, what will be the impact of this directive on Investigator Initiated Research projects fully or partially performed in your centre, in terms of NUMBER of studies?



Note: Based on answers from “well aware” respondents, number varying between 138 and 121

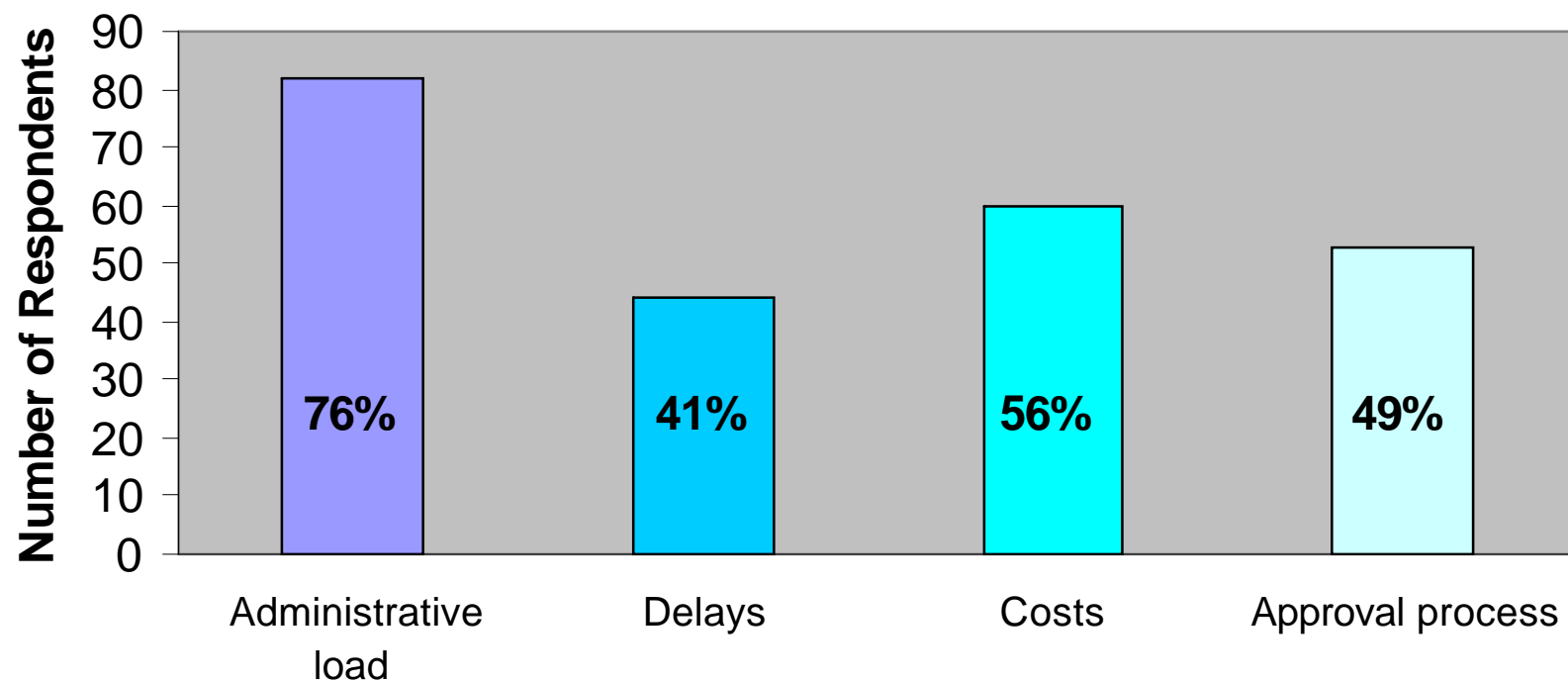
# By which % do you expect the number of studies to drop? (based on 52 respondents predicting a drop)

You are well aware of the Directive, and you expect a decrease in the number of studies - by which % do you expect it to drop?



## Reasons for impact

If you do consider that this Directive may adversely affect the Investigator Initiated Research output in your center, what would you give as major reasons (tick any number of boxes)?



## **ESC EU CTD Survey - Summary**

- **The poll was a fast and economic way to obtain opinions on the EU Clinical Trial Directive from pre-identified clinical researchers**
- **1005 clinical researchers responded (Out of a total of 10 009 emails sent - a response rate of 10%, considered high for an electronic poll)**
- **14% of respondents had good knowledge of the Directive**
- **There is a considerable lack of knowledge about the Directive in 86%**
- **Of those who know the Directive, their principal feedback predicts a sizeable downturn in the number of Investigator initiated research projects in the EU as result of the Directive. (majority predicts a reduction of 25-75%).**
- **The principal causes cited are administrative overload and increased costs, which investigator centres cannot absorb.**

# Cardiovascular Research in Europe

- **Other Potential Threats to Cardiovascular Research in Europe**

# Cardiovascular Research in Europe

- **Aspects of Research emphasis and assessment:**

- Biomolecular laboratory-based science and genomics dominates research applications, funding and training
- Critical loss of expertise in patient-orientated clinical research, cardiovascular physiology, imaging, and population sciences

# Cardiovascular Research in Europe

- **Compounded by current methods of Research assessment:**
  - Research assessment tools – place crude emphasis on “quality” assessments based on publication in “high impact journals”
  - Undermines research in specialist and/or emerging areas of clinical medicine
  - Discourages research training in “unfashionable” but important disciplines

# Cardiovascular Research in Europe

## Fewer trainees in Clinical Academic posts

- Clinical Academic career is “less attractive”
- Medical school education places less emphasis on classical training in basic sciences; biochemistry, physiology, anatomy
- Research Training posts and funding have diminished
- Applications for fellowships in clinical patient-orientated research and population sciences have declined rapidly
- Career progression in Academic medicine has become uncertain
- Tensions between clinical service commitments and research have increased – Research time is “less protected”

# Cardiovascular Research in Europe

## Fewer trainees in Clinical Academic posts

### - The Irony:

- The translation of science into medicines is happening faster than ever before
- Appropriate and effective translation requires skilled clinical scientists
- We live in the age of “Evidence-based medicine”
- Good evidence comes from the framing of appropriate questions, and well-designed and well executed clinical research
- Clinical academic excellence is not a luxury – it is essential to advance patient care

# **“Resuscitating” Cardiovascular Research in Europe**

## Summary

- European CTD: Was well intentioned but could have a devastating impact on “investigator-led” clinical academic research and the moral of the research environment in Europe
- **There is a need to:**
  - Alleviate the administration and financial load from the research centres
  - Solve the “sponsor problem” for investigator-initiated/led research
  - Provide information and training on the Directive’s implementation

# **“Resuscitating” Cardiovascular Research in Europe**

## Summary

- Crisis in Clinical Academic Medicine:
- Concerted action required to;
  - Increase funding for research training posts in clinical academic medicine
  - Urgently address the shortfall in funding of research and training posts in clinical, patient-orientated research, cardiovascular / integrated physiology and population sciences
  - Review current Research assessment tools
  - Improve the career prospects of clinical academic medicine
  - Consider the establishment of a European Research Council (vv NHLBI) with a major focus on re-invigorating Clinical Cardiovascular Research