eCTD Experience: Industry Survey Results

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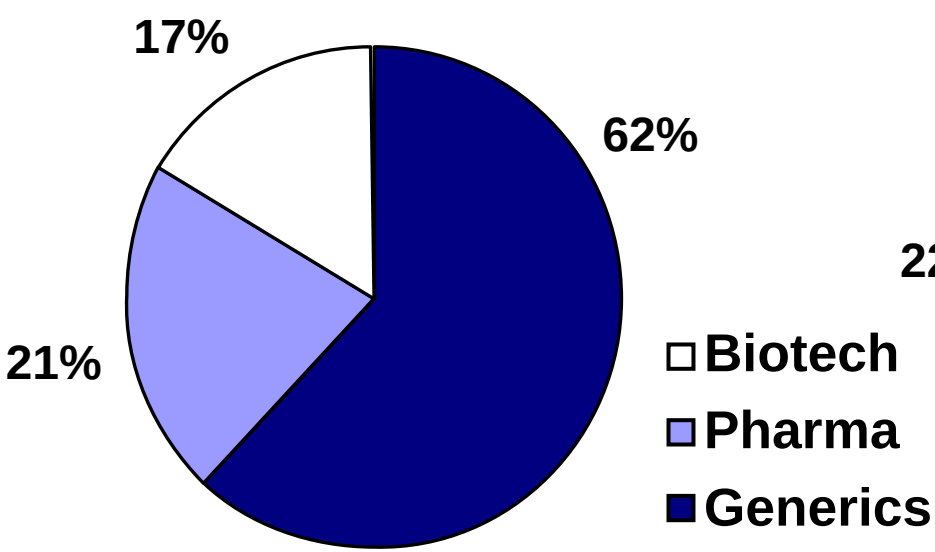
CAPRA
21-22 February 2006

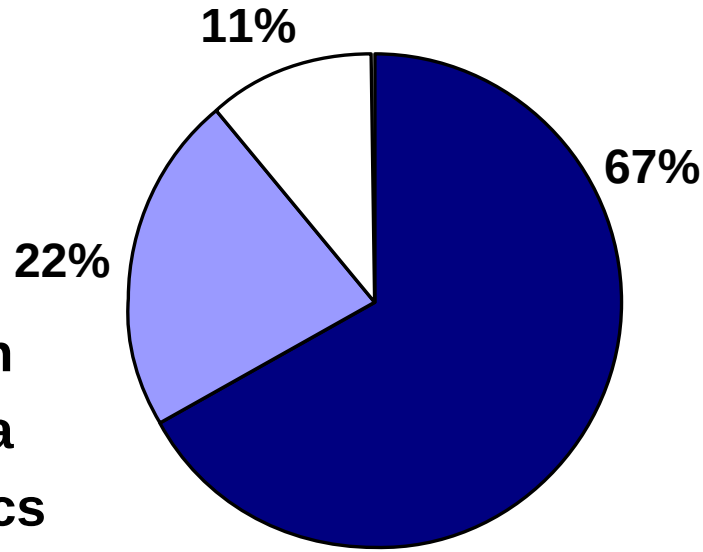
Why Conduct an Industry Survey on eCTD Use?

- As a contract organisation, our planning requires understanding what is important in the industry now and in the future.
  - The number of eCTD submissions per regulatory agency cited during conferences is not always easy to interpret and is difficult to extrapolate to industry in general.
  - The goal of the survey was to provide a rough estimate on present and future industry eCTD submission strategies with respect to company type, size, and country (of head office) and the regulatory agency(ies) of submissions.

Surveys Sent and Responses Received by Company Category

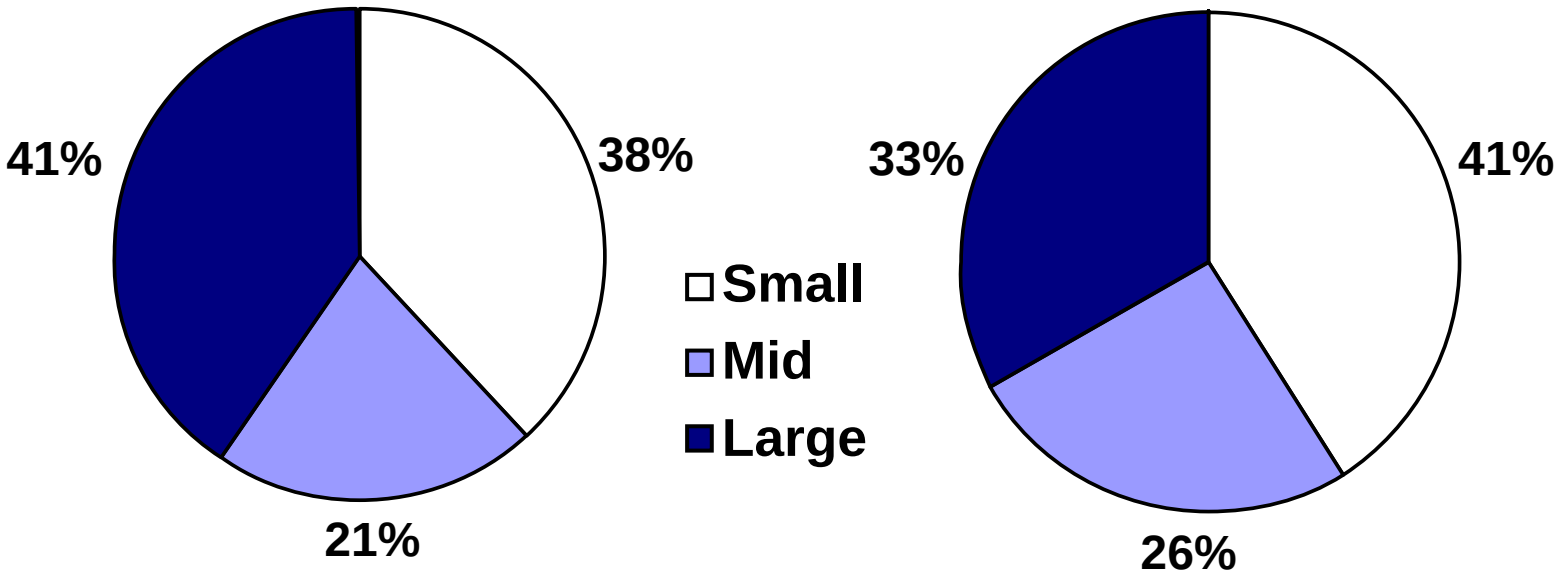


Surveys Sent (n=84)



Responses (n=27)

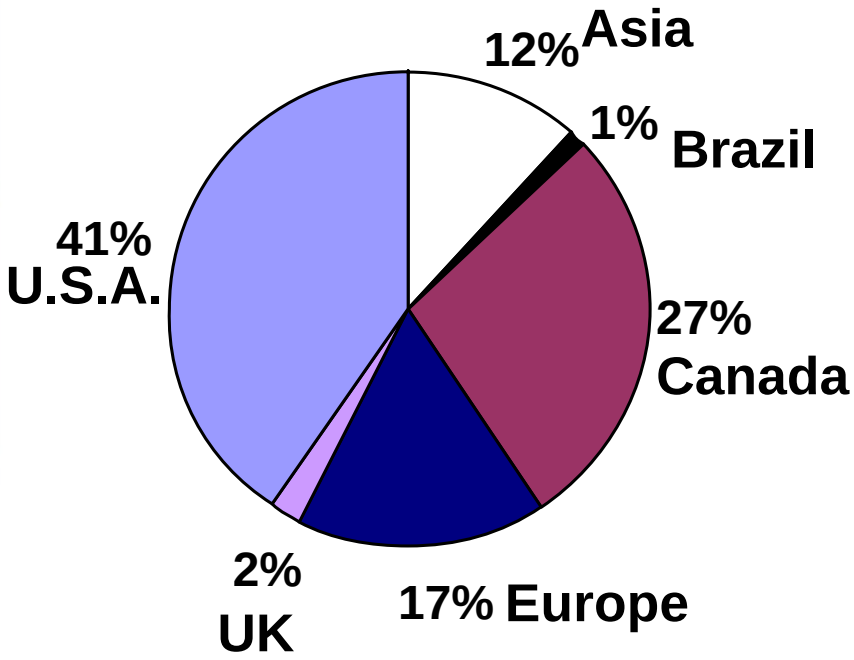
Surveys Sent and Responses Received by Company Size



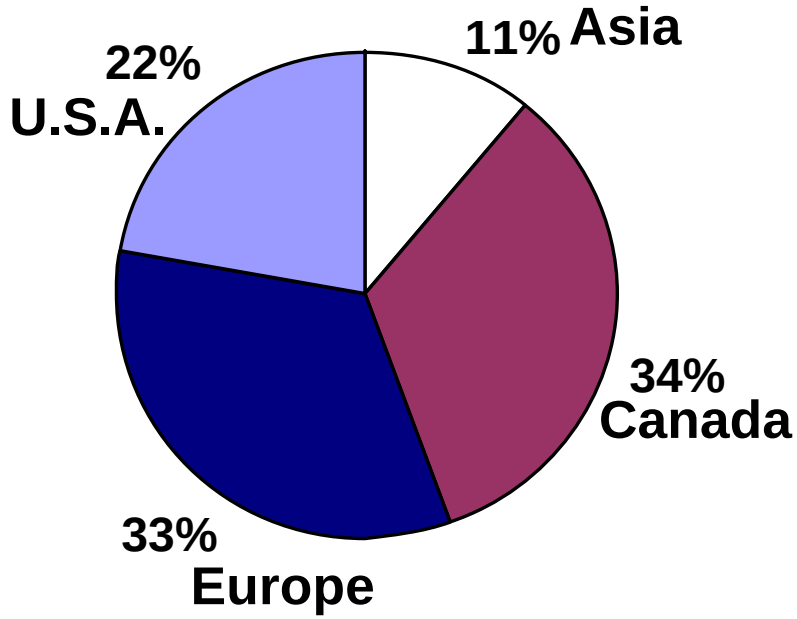
Surveys Sent (n=84)

Responses (n=27)

Surveys Sent and Responses Received by Country (Company Head Office)



Surveys Sent (n=84)

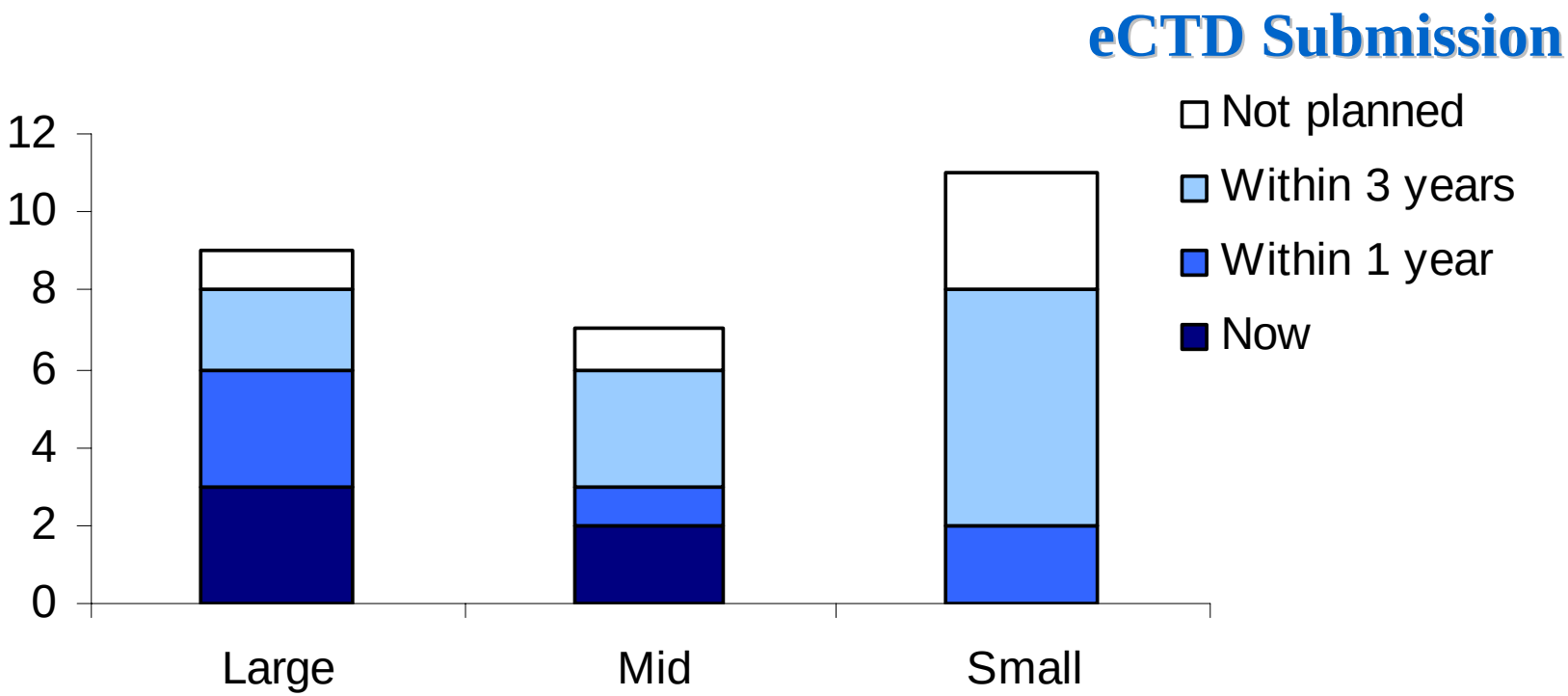


Responses (n=27)

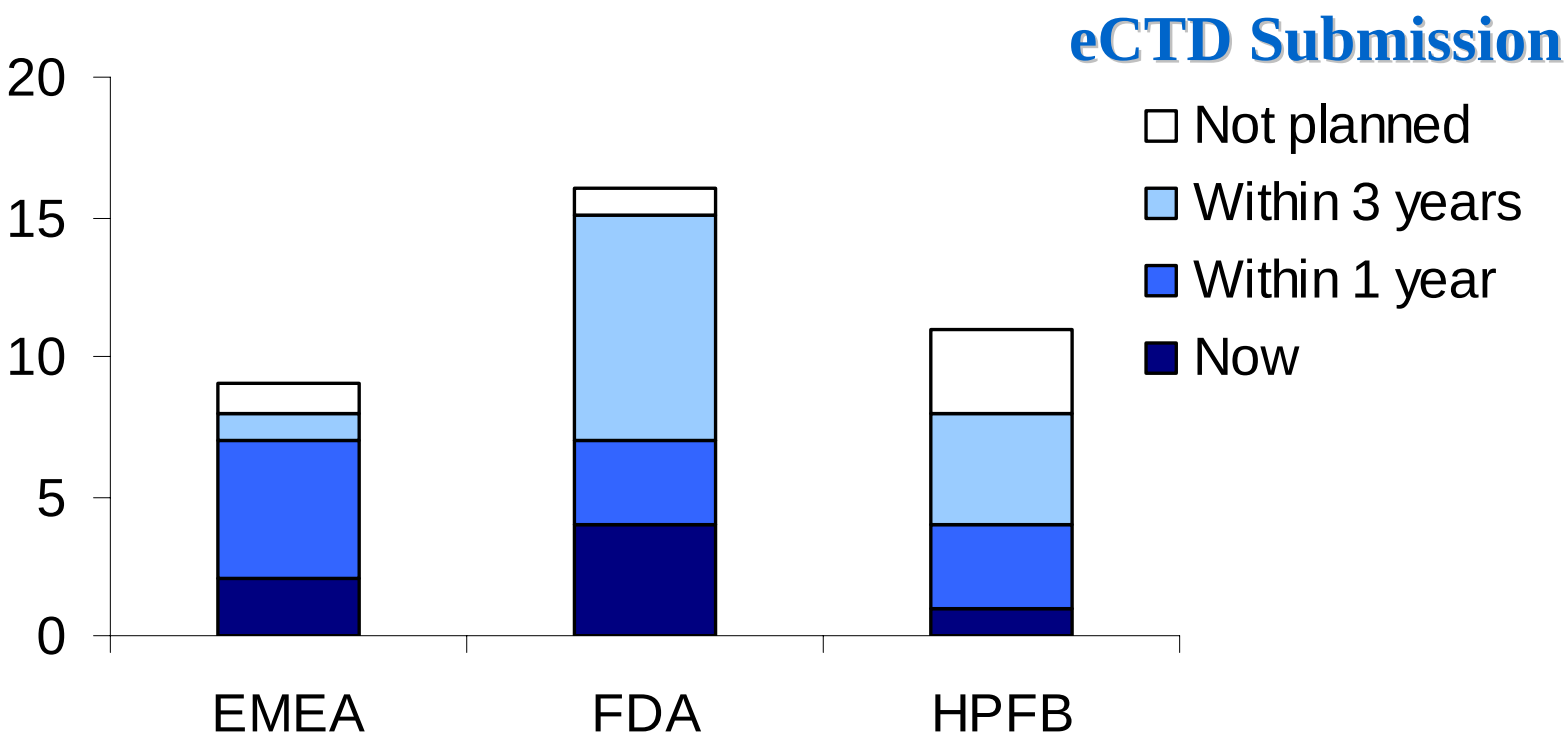
What Types of Questions Were Asked?

- Companies were asked:
  - to rate their eCTD readiness (already filing eCTD or if planning to).
  - what regulatory agency(ies) they usually file with.
  - whether they planned on preparing/managing their submissions in-house.
  - what they consider to be the factor(s) that were most limiting with respect to eCTD readiness.

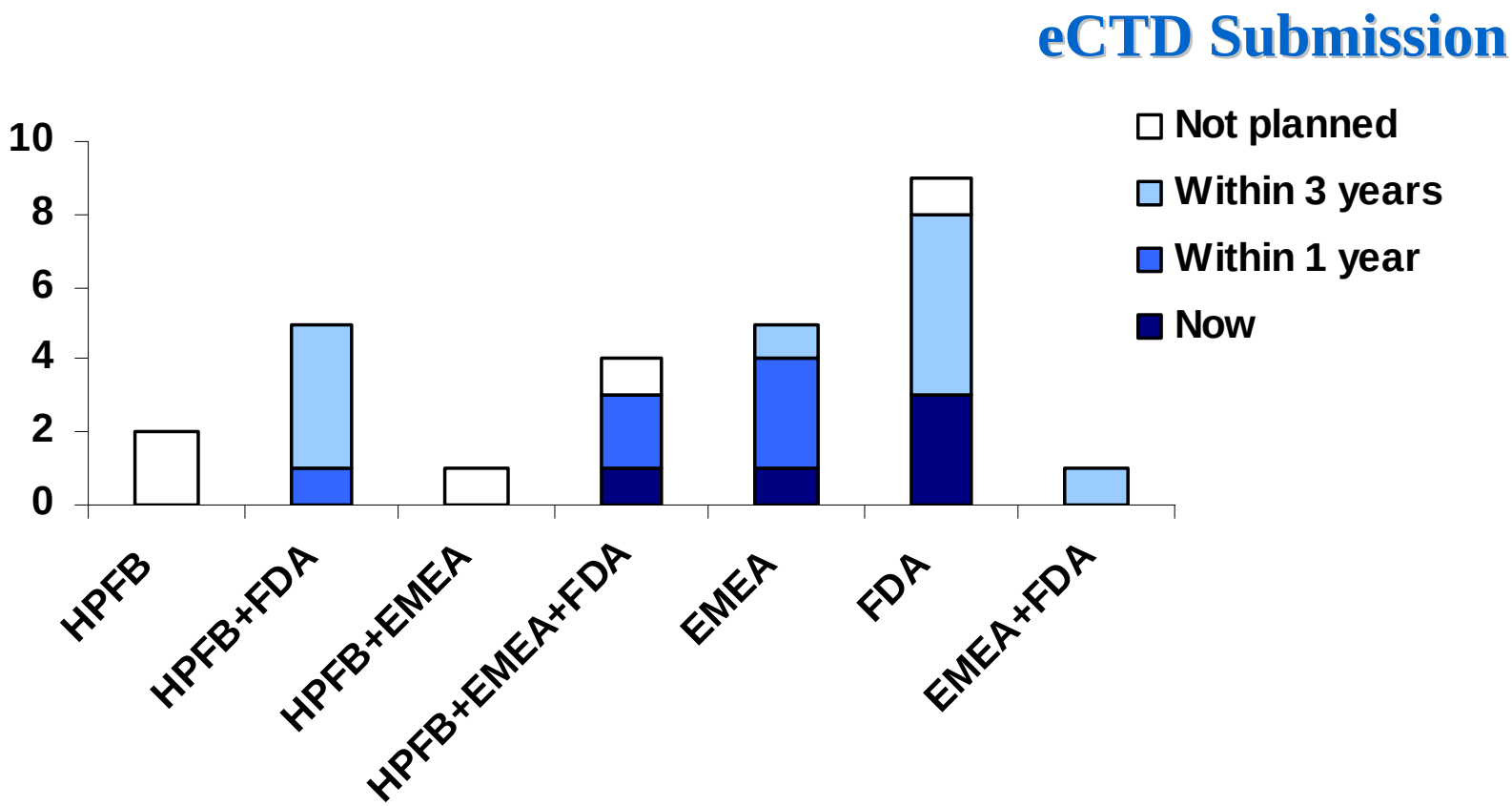
eCTD Readiness by Company Size



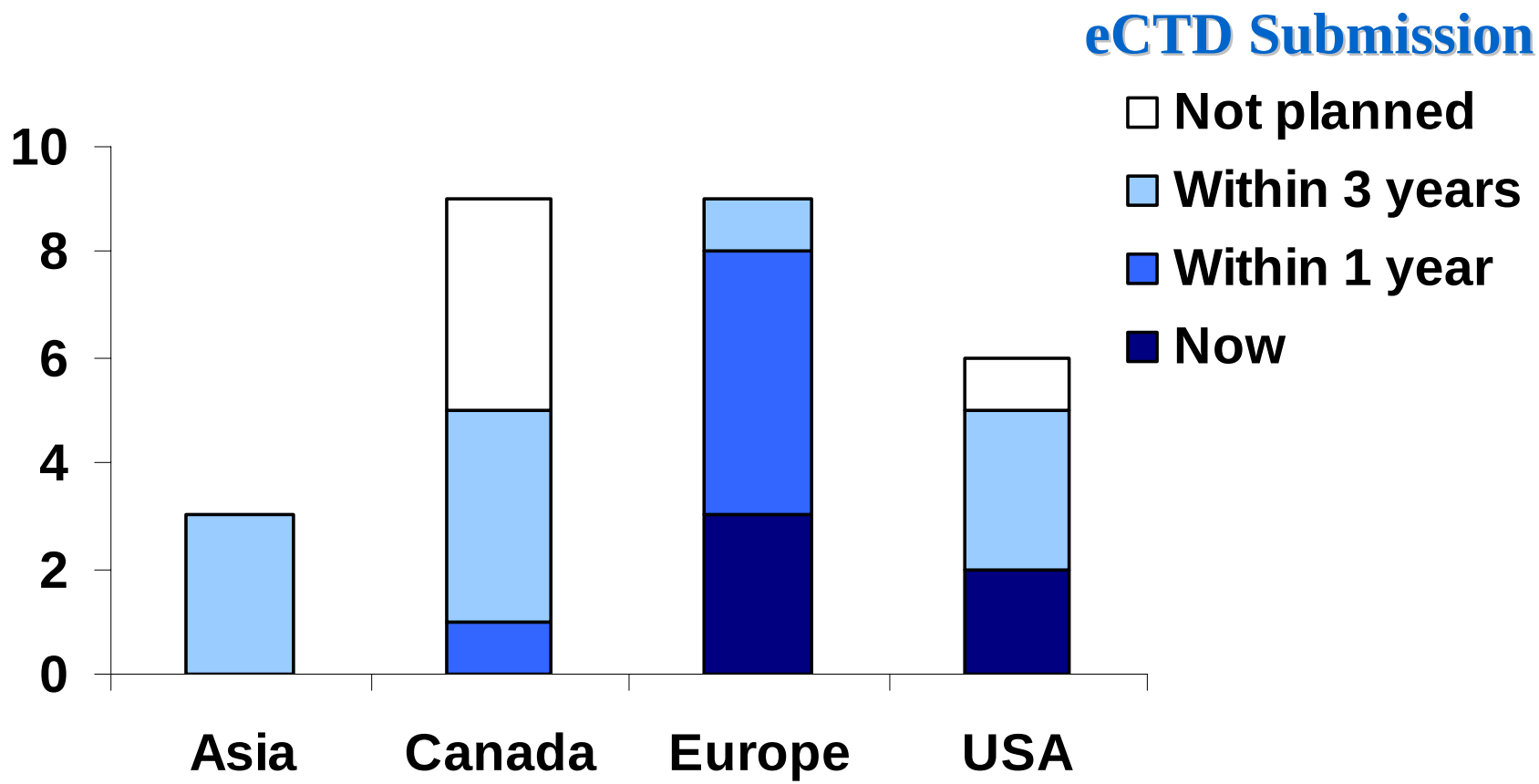
eCTD Readiness by Usual Regulatory Agency of Submission



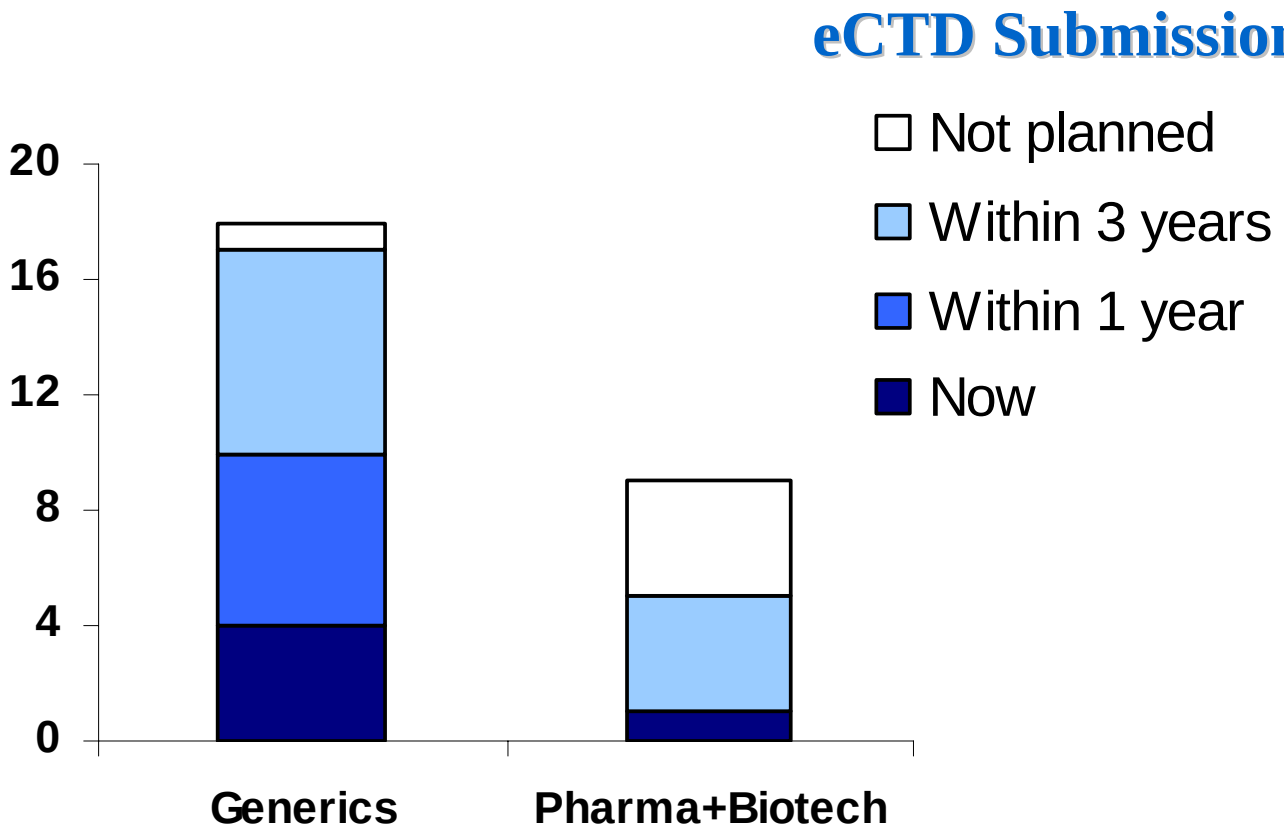
Companies Regularly Submitting to More Than One Regulatory Agency



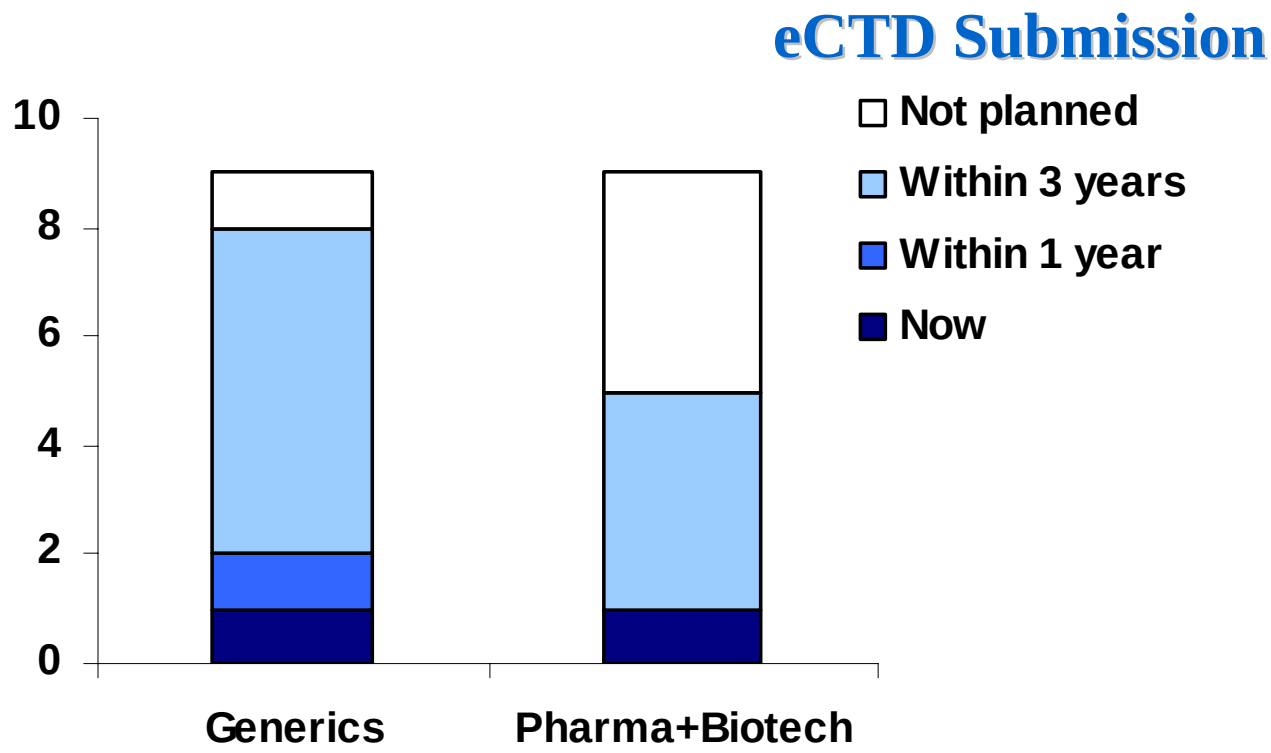
eCTD Readiness by Country (Company Head Office)



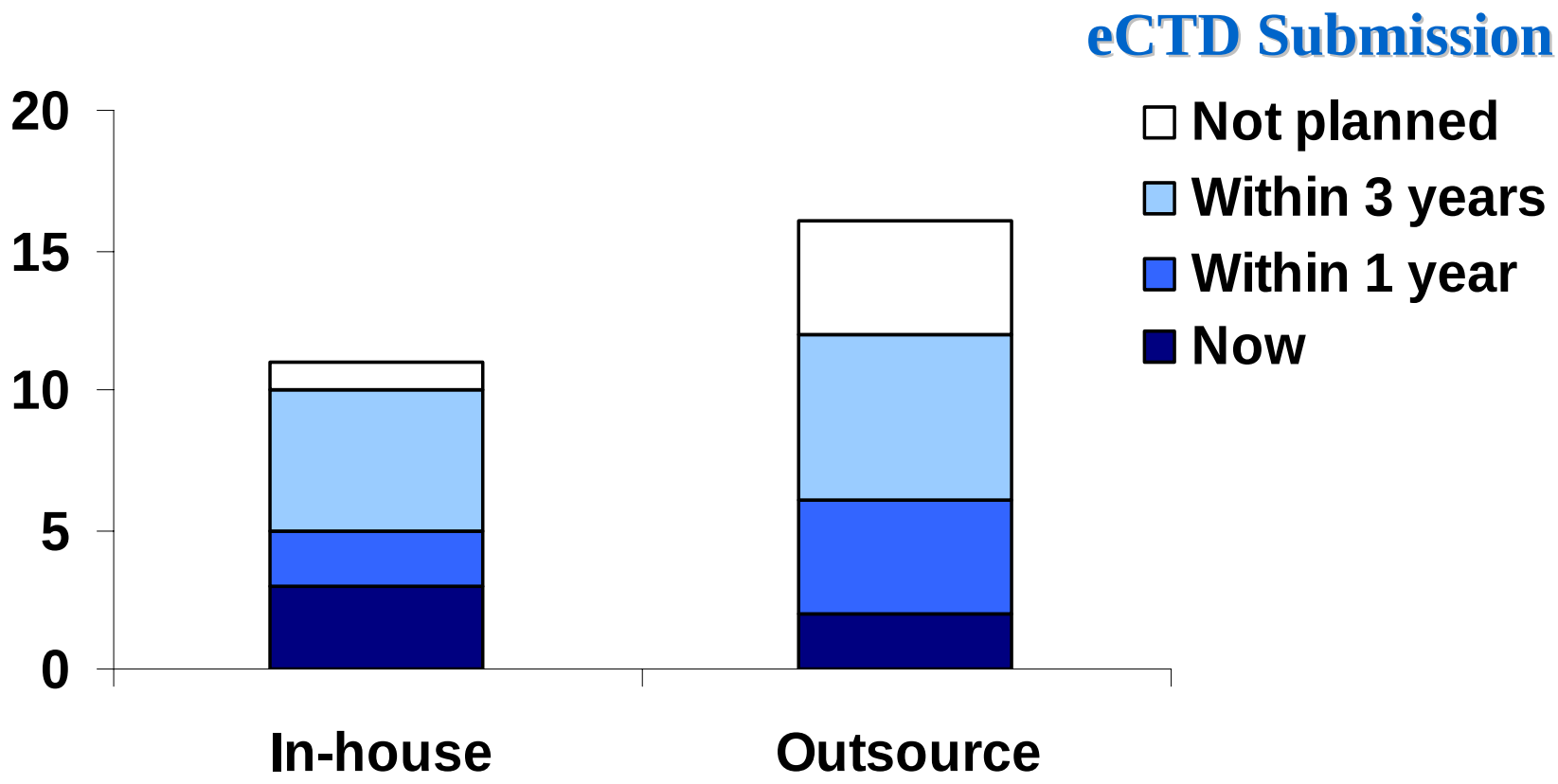
eCTD Readiness by Company Category



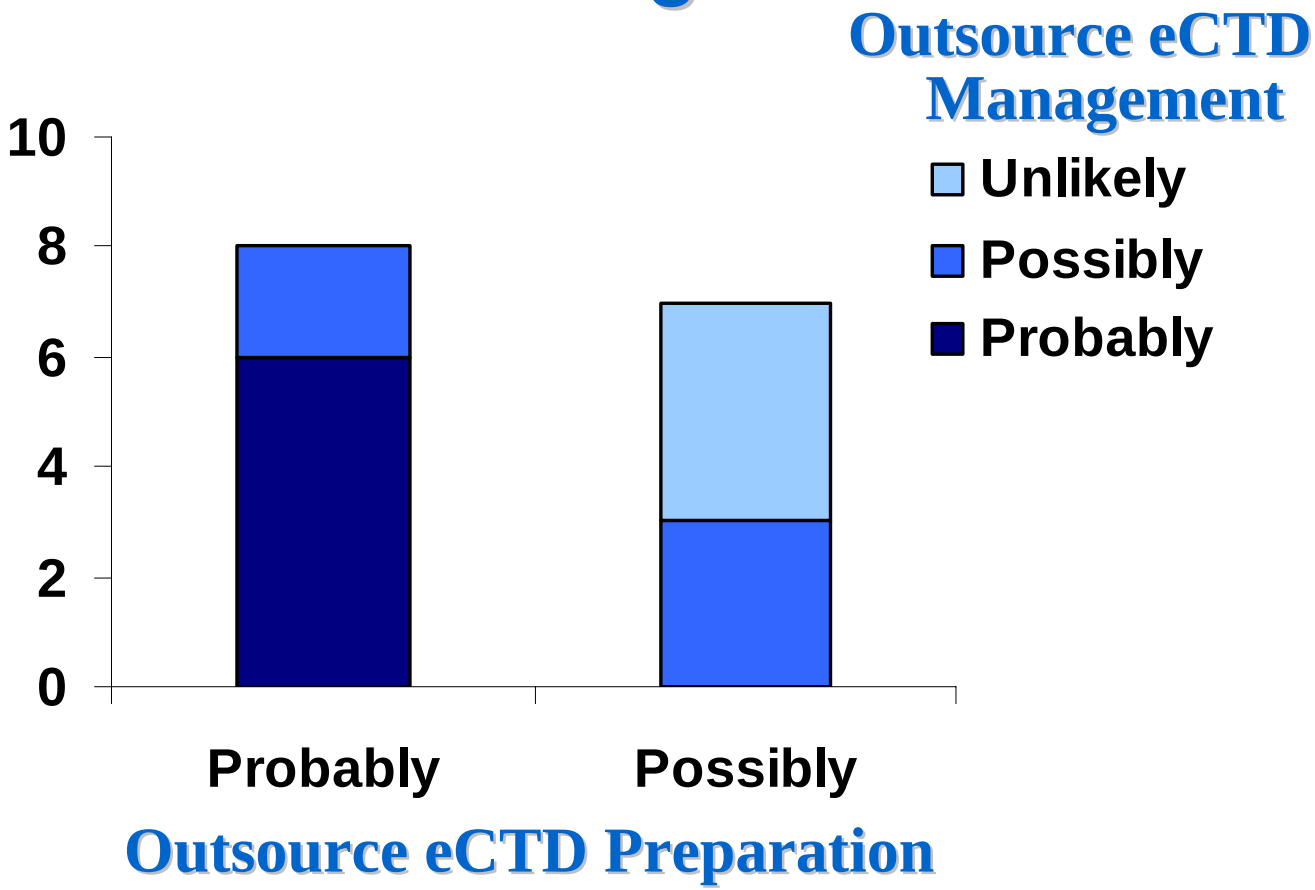
eCTD Readiness by Company Category (Excluding European Companies)



Effect on eCTD Readiness by Planned In-house Versus Outsourced Submission Preparation



Readiness by Industry to Outsource eCTD Management



Factors Limiting Industry Movement Towards eCTD Submission

- Factor most cited (approximately 50% of responses to this question)
  - Software; IT support and associated costs, including training
- Other factors cited
  - Other priorities
  - Strategy is under review
  - FDA does not mandate it
  - FDA division did not encourage it

Conclusions

- ✓ Larger companies tend to be more eCTD ready than mid-sized or small companies
- ✓ European companies tend to be more eCTD ready than companies from Asia, U.S.A., and Canada
- ✓ Companies possibly willing to outsource submission preparation display hesitation to outsource management
- ✓ Software and IT support (associated costs and training) cited most as factors limiting movement towards eCTD.