



## BACKGROUND

ESPAC-3 (v2) compared survival following adjuvant gemcitabine versus 5-FU/FA in 1030 patients with ductal adenocarcinoma

TRIAL IS NOW CLOSED TO RECRUITMENT

ESPAC-3(v2) closed for recruitment to this group of patients in December 2006.

Preliminary survival analysis is expected once the event rate reaches 53%

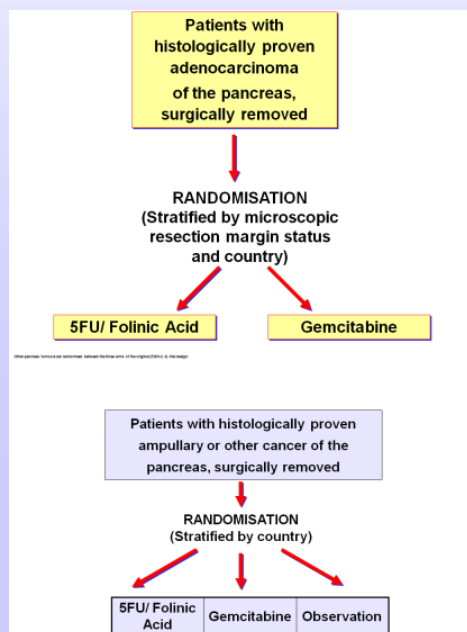
## STUDY DESIGN

The ESPAC-3(v2) trial design evolved from the final analysis of the ESPAC-1 study, which concluded:

- No significant benefit for adjuvant chemoradiotherapy
- Statistically significant benefit for adjuvant chemotherapy
- Overall 5 year survival of 21% with adjuvant chemotherapy
- Overall 5 year survival of 8% with no adjuvant chemotherapy

## INCLUSION CRITERIA

- Histologically proven adenocarcinoma of the pancreas
- No evidence of ascites, liver or distant metastases
- WHO  $\leq 2$  and Life expectancy of more than 3 months
- Able to attend for adjuvant therapy & follow-up
- No previous or concurrent malignancy diagnosed
- Written informed consent given



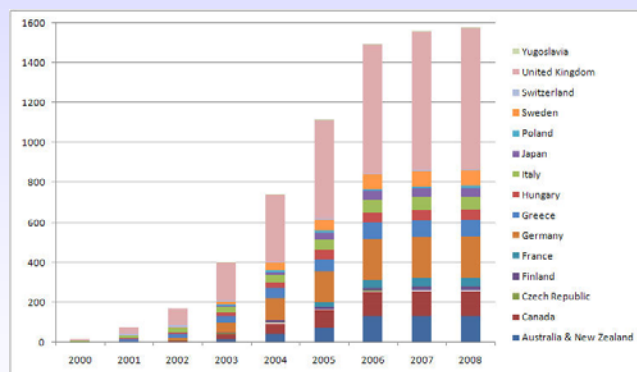
## STATISTICAL CONSIDERATIONS

The primary end-point is the length of survival. Secondary endpoints are toxicity, quality of life and 5-year survival rate.

515 ductal patients in each group will permit detection of a 10% difference in 2-year survival rates between the 2 chemotherapy arms ( $\alpha = 0.05$ , 1-B = 90%).

## LATEST UPDATE

| TUMOUR TYPE           | 5FU | GEM | OBS | TOTAL TRT | OVERALL TOTAL |
|-----------------------|-----|-----|-----|-----------|---------------|
| Ductal Adenocarcinoma | 551 | 537 | 61  | 1088      | 1149          |
| Ampullary             | 101 | 96  | 103 | 190       | 300           |
| Other                 | 42  | 48  | 41  | 90        | 131           |
|                       |     |     |     |           | 1580          |



## FOR FURTHER DETAILS PLEASE CONTACT

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