



Central South Coast
Cancer Research Network

**Validation of a disease-specific questionnaire module
in assessing the quality of life of patients with G.I.-
related NET.**

Phase 4 Study

NET / Carcinoid Tumours

Clinical Trial Co-ordinator Liz Friend

Lead Clinician Dr J.K. Ramage

Copenhagen Meeting November 2005



G.I.NET21

- Phase 3 report accepted subject to time scale recommendations.
- Time frame of 1 week except sexuality question.
- Patients preference for 1 or 4 week time scales in Phase 4 study.



Changes to scales for G.I.NET 21

use negative scoring for all questions so severe symptoms means high score.

Symptom Scales

- Endocrine (3)
- G.I. (5)
- Treatment (3)

Symptom Single Items

- Muscle/bone pain (1)
- Body image(1)

Psychosocial Scales

Social (3)

Disease-related
worries(3)

Other Single Items

- Sexuality (1)
- Communication(1)



Change to Q50

Change Q 50 so scoring is uniform.

Change wording from “ Has the information about your disease and treatment been adequate?” to “Did you have difficulty obtaining adequate information about your disease and treatment?”



Translations

- Complete in Dutch, French, German, Italian and Swedish, (but will need Q50 changing)
- Requested in Polish.
- Others for current Ipsen trial ,eg, Spanish.



Phase 4 validation study

Aims of Study

- Test scale structure, reliability and validity of G.I.-NET module(G.I.NET21)
- Assess quality of life using C30 and G.I.NET21 before and after various treatments
- Plan for 400 patients to be recruited (based on planned statistics by Dr Ghasem Yadegarfar)



Inclusion and exclusion criteria

Primary	Metastases	Hormones
Gut	liver	With
Lung	liver/abdominal	Or
Pancreas	with/without	Without

- NET diagnosis from histology or radiology
- All patients will be starting a treatment for G.I.NET, and will be put into groups 1, 2 or 3 depending on the treatment they receive.



Assessment schedule

1 st assessment	2 nd Assessment	3 rd assessment
Within 3 weeks before treatment	3 months (+/- 3 weeks)	6 months (+/- 3 weeks)

- ?Time points delayed for prolonged therapy
Eg, chemotherapy, radio metabolic therapy



Treatment Groups

**Group 1: Somatostatin analogues or interferon-
long term continuous treatment.**

- Patients be SMS or interferon naive
- Dose escalation is allowed
- Other treatments avoided, if possible.



Treatment Groups

Group 2: Radiometabolic therapy or systemic chemotherapy-2-6 treatments.

- ?Assessments can be delayed by up to 14 days.
(not done during week of and week after treatment)

Group 3: Embolisation(hepatic artery or chemotherapy) or liver surgery-single treatment.



Treatment Groups

For Groups 2 and 3

Not had group 2 or 3 treatment within past 6 months

Patients can be on a stable dose of group 1 treatment
but dose must not change by more than 50% for
the duration of the study.



Data Forms

- Sociodemographic data
 - ?need to ask questions on
 - marital status
 - employment
 - education



List of investigators

- Dr Ramage-Basingstoke and London,UK.
- Louise Jones-Liverpool, UK.
- Colin Johnson-Southampton, UK.
- ? 2 other sites in UK(Birmingham,London).
- Dr Joy Ardill, Northern Ireland
- Dr Sezar and Dr Fleissner-Germany
- ?Dr Koller-Germany
- Dr Falconi and Dr Bettini- Italy
- ?Prof Pino-Italy
- Dr Taal and Dr Zuetenhorst-The Netherlands
- Dr Larsson-Sweden
- Dr Jeziorski- Poland
- ?Dr Emanuel Christ- Switzerland



Future Plans

- **Investigator meeting**

Paris

Wednesday 3rd May 2006

?Ipsin to sponsor